IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF TENNESSEE

AT CHATTANOOGA

KAREN GUTHRIE, individually and on behalf of the ESTATE of DONALD GUTHRIE,

Plaintiff,

v. 1:11-CV-333

GREGORY BALL, M.D.,

Defendant.

Chattanooga, Tennessee
October 28, 2014

BEFORE: THE HONORABLE SUSAN K. LEE,
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

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SECOND DAY OF TRIAL

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(Court was again in session, outside the presence of the jury.)

THE COURT: Good morning. I hope some of you got to enjoy that beautiful sunrise today. The full panel of jurors is not here yet, so I thought I would address the objection you had. Are you playing the video first or putting on a witness first?

MR. MILLER: Playing the video first, Your Honor.

THE COURT: Okay. The Court's understanding is that the objection of the defendant has been made pursuant to Rule 803.18, 401, 402, and 403. I don't see, really, how the exception to the hearsay rule, 803.18, could apply to the doctor's description of the Isenschmid -- what is it called again?

MR. MILLER: Isenschmid article.

THE COURT: Isenschmid article, because he specifically says it's not reliable, so I think that his testimony about what that article says is in fact hearsay. The Court will exclude the portions of Dr. Metcalfe's testimony regarding what the article says. However, Dr. Metcalfe's statements regarding whether that article changed his mind as to Mr. Guthrie's cause of death does not appear to be hearsay. It appears to be his own statements, and I don't see a basis for excluding them. I don't see that they're more prejudicial than probative based on the portions that were provided.

Now, to the extent that the lawyers need assistance on figuring out which lines my ruling would impact, I would be surprised to hear that. What you figure -- I mean, we can go, I guess, line by line if you can't come to an agreement, but while we wait for the juror, I suggest that you pull out the two highlighted portions. I think it's -- I think it's going to be pretty obvious what the ruling impacts and what it doesn't. And I don't know whether somebody wants to actually play the few lines that would be allowed to come in given the lines that will not be coming in, but it does appear to me that a small portion of the highlighted transcripts that you provided me yesterday would be allowed to come in if somebody actually wanted to without further reason.

The only other thing I need to tell you while we wait here, to try to use the time productively, is that we have a grand jury meeting today. It typically does not take me all that long to take a return, and I don't want to have our grand jury waiting unnecessarily. So at some point in the proceeding, I may need to take a break to take the grand jury return and, you know, if that happens, it happens. Hopefully I can do the return at lunch, but as I said, that's all dependent on what the grand jury has got going on today and how long it takes them to do their work.

Is there anything else?

MS. BOYCE: No, Your Honor.
MR. MILLER: No, Your Honor.
THE COURT: All right. Mr. Eslinger, would you see if we can bring the jury in?
THE COURTROOM DEPUTY: Yes.
(The jury returned to open court.)
THE COURT: Good morning.
JURORS: Good morning.
THE COURT: I hope some of you got to enjoy that beautiful sunrise I saw coming in.
A JUROR: That was a big sun, wasn't it?
THE COURT: Yes. Oh, you don't need -- we're standing for you. Call your next witness.
MR. MILLER: Call Medical Examiner James Metcalfe by video to the stand.
THE COURT: Ladies and gentlemen of the jury, you are about to be played videotaped testimony of a witness. The fact that it's being presented by videotape has been agreed to by the parties. It includes both sides' presentation of the evidence, and as I'll instruct you further at the conclusion of the case, you're going to be able to consider this evidence as if Dr. Metcalfe was here on the stand. It makes no difference in the evidence that it's being presented by videotape. If any of you have any difficulty seeing your monitor or hearing the videotape, please don't wait, don't hesitate,

raise your hand, because I want to make certain that all the monitors are working. I think I've placed you where I know that they do work, but it's video equipment, so you never know. All right, Mr. Miller.

(A portion of the videotaped deposition of James K. Metcalfe, M.D., was played in open court.)

THE COURT: Why don't you turn it up. He's a little soft spoken.

MR. MILLER: Let me see how I do that here.

THE COURT: All right, Mr. Miller, we've got it handled.

MR. MILLER: Okay. You want me to start it over, Your Honor?

THE COURT: Go ahead.

(A portion of the videotaped deposition of James K. Metcalfe, M.D., was played in open court.)

MR. MILLER: Your Honor, we're just going to put on the headphones until we get through the part you ruled out.

(A further portion of the videotaped deposition of James K. Metcalfe, M.D., was played in open court.)

MR. MILLER: There's a second part to the videotape, Your Honor.

THE COURT: Well, I can't see that clock from here. Is it --

MR. MILLER: 10:20.

THE COURT: 10:20? Why don't we take the mid morning break. I'll give you a chance to stretch out a little bit. And you can cue it up. We'll keep this break very short, so maybe five or ten minutes. Mr. Miller, you can go ahead and cue up the next portion.

(Recess taken.)

THE COURT: How long is this segment?

MR. MILLER: It is --

THE COURT: Generally.

MR. MILLER: -- an hour and nine minutes. May I proceed, Your Honor?

THE COURT: Yes.

(A further portion of the videotaped deposition of James K. Metcalfe, M.D., was played in open court.)

THE COURT: Mr. Miller, go ahead and pause that when you get to the right spot. I want to explain to the jury that this isn't an equipment malfunction. It's a portion of testimony that is not being presented to you.

(The remainder of the videotaped deposition of James K. Metcalfe, M.D., was played in open court.)

THE COURT: I think you cut off the last word he said.

MR. MILLER: Yes, and I apologize, Your Honor.

THE COURT: I think rather than restart it, I think that given the shortness, why don't you read the last word. I

don't know how long it would take you to get it back to the last word.

MR. MILLER: The last answer is, "Well, you answered that question already" --

THE COURT: No, you just read that wrong.

MR. MILLER: I did? Starting at line 14.

THE COURT: Yes, "Well, you asked," not "Well, you answered."

MR. MILLER: "Well, you asked that question already and I said you presume that it was therapeutic, but therapeutic level because he was still alive."

THE COURT: Any need to replay it to get that last word?

MS. BOYCE: No, Your Honor, that's fine.

THE COURT: Call your next witness.

MS. BOYCE: Before we leave this, I would like to admit into evidence that we discussed in Dr. Metcalfe's deposition, his autopsy report and his personal files from which he testified from.

THE COURT: Any objection? And what are the numbers on that?

MS. BOYCE: J-1 and J-50.

MR. MILLER: As long as they've been redacted. And we also want to admit the death certificate at the same time.

THE COURT: Why don't you talk about it at lunch and

make sure you've got what you wanted admitted and we'll deal with it, but it sounds like there will be a few documents from the deposition testimony that will be admitted. Call your next witness.

MR. MILLER: Okay. Our witness is outside under the rule, so --

THE COURT: You can stretch if you want to in between. Everybody pops up.

THE COURT: This is your witness?

MR. PATE: Yes, Your Honor, it is. The plaintiff calls Dr. Christopher Grubb.

THE COURT: Dr. Grubb, come forward, stand next to the witness chair and raise your right hand to be sworn in.

CHRISTOPHER THOMAS GRUBB, M.D.,

called as witness by the plaintiff, being first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. PATE:

Q Good afternoon, Dr. Grubb.

A Good afternoon.

Q Could you please state your full name for the jury.

A Christopher Thomas Grubb.

Q And you are a licensed physician; is that right?

A Yes.

Q What is your specialty?

A Anesthesiology and pain management.
Q And how long have you been practicing as a physician?
A About 14 years.
Q And you are here today offering testimony as an expert on behalf of my client, Karen Guthrie; is that right?
A Yes.
Q Why were you hired in this case?
A I was hired to review medical reports related to the care of Mr. Donald Guthrie and render an opinion regarding the standard of care.
Q You might push the microphone away from you a little bit. Looks like you've got some feedback there. And you're being paid for your time; is that right?
A Yes.
Q How much are you charging to be here today?
A $500 an hour with a $2,000 per day minimum.
Q And you testified you reviewed the medical records of Mr. Guthrie; is that right?
A Yes.
Q And did you charge money to do that?
A Yes.
Q Did you also previously give your deposition in this case?
A Yes.

Q Did you charge money to do that?
A Yes.
Q How much total time, would you say, Doctor, at this point that you have charged for your involvement as an expert witness in this case?
A I think somewhere around 16- or $17,000 total.
Q I want to ask you a little bit about your credentials, starting off with: Where did you do your undergraduate work?
A Davidson College in Davidson, North Carolina.
Q And what year did you graduate?
A 1996.
Q And where did you go to medical school?
A Brody School of Medicine at East Carolina University in Greenville, North Carolina.
Q And what year did you graduate?
A 2000.
Q Did you do a residency?
A Yes.
Q What did you do your residency in?
A Anesthesiology.
Q And where did you perform your residency?
A The University of Virginia in Charlottesville, Virginia.
Q And how long was your residency program?

A Four years total.
Q And you said the focus, the area of medicine that you were focused on during your residency was anesthesiology?
A Yes, with a subspecialty focus in pain management.
Q Are you currently board certified?
A Yes.
Q And in what areas are you board certified?
A I'm board certified in anesthesiology by the American Board of Anesthesiology and board certified in pain medicine by the American Board of Pain Medicine.
Q And when were you first board certified in anesthesiology?
A 2005.
Q And what about pain management?
A 2007.
Q How long total, Doctor, have you been practicing in the field of pain management?
A Ten years since residency.
Q Do you currently hold any professorships?
A Yes, an affiliate assistant professor of anesthesiology at Brody School of Medicine.
Q Have you held any other professorships in the past?
A Yes, at the University of Virginia. After finishing residency there, I also had an affiliate assistant professorship in anesthesiology.

Q Have you ever lectured or taught in the field of pain management?
A Yes.
Q And what can you tell us about that?
A Well, I lectured to medical residents at Womack Army Medical Center during the three years that I was in the army at Fort Bragg, North Carolina, on the topics of chronic pain management and acute pain management, and then I lecture in more informal ways in my current practice with medical students at Brody School of Medicine and with a small number of emergency medicine and internal medicine residents as well as nurse anesthesia students.
Q And where is Brody School of Medicine located?
A Greenville, North Carolina.
Q Have you ever published in the field of anesthesiology?
A Yes.
Q And what can you tell the jury about that?
A Well, I did some research when I was at the University of Virginia on a number of topics and published various manuscripts related to those topics, ranged from obstetric anesthesia to regional anesthesia to pain management.
Q You currently practice in Greenville, North Carolina; is that right?

A Yes.
Q And how long have you practiced there?
A A little over seven years now.
Q And having practiced there for a little over seven years, are you familiar with the standard of care that is applicable to anesthesiologists and pain management specialists in Greenville, North Carolina?
A Yes.
Q North Carolina actually borders eastern Tennessee; is that right?
A That's right.
Q Have you done any research in terms of size and demographics of Chattanooga, Tennessee?
A Yes.
Q Is it fair to say that Greenville is roughly about the same size as Chattanooga?
A In general terms, it's roughly the same size.
Q What about the comparability of population between the two?
A Very comparable in terms of population and the medical community as well.
Q Is it fair to say that Greenville and Chattanooga are similar to one another as far as the communities themselves are concerned?
A Yes.

Q What about in terms of medical infrastructure?
A They're very similar. In our area, we have a large medical center with a little over a thousand beds. In Chattanooga, I think they have multiple hospitals that aren't quite as large as our one hospital, we consolidated into one hospital, but as far as the medical -- the availability of medical services, advanced services, specialized services, it's very similar.
Q And the community standard of care that applies to pain management physicians in Greenville where you practice and in Chattanooga where we're here today, would you say they're comparable?
A Yes.
Q The local standard of care for treatment of patients with fentanyl patches, which we'll be talking about, in Chattanooga, are they the same here as they would be pretty much anywhere else?
A Yes.
Q Have you formulated opinions in this case based on your review of the records and depositions as to whether or not Dr. Ball and his staff complied with those standards in their care and treatment of Donald Guthrie?
A Yes.
Q And are the opinions that you are going to be offering the jury today about Dr. Ball and his staff's care

and treatment of Donald Guthrie, are they based on the community standards of care that are applicable to pain management physicians in Chattanooga and elsewhere?

A Yes, they are.

Q Why don't we start off, Doctor --

MR. MILLER: Your Honor, I need to approach the Court by the bar or outside the presence of the jury to address a matter.

THE COURT: Does it need to be addressed right now?

MR. MILLER: It does.

THE COURT: All right. What we'll do is we'll take our lunch break now. Ladies and gentlemen of the jury, we've -- I'm pretty sure that it's straight up noon right now. Did you find an hour yesterday to be -- does anybody need more than an hour? All right. Why don't we plan to reconvene at 1:00 with you.

And again, I just want to remind you, please don't talk about the case, don't research the case. Just go enjoy this beautiful, I'm afraid, last of the warm weather if you can.

(The jury was excused from open court.)

MR. BROCK: Your Honor, I waited before he began to ask opinions. Your Honor, pursuant to the trial order, on January 3rd --

THE COURT: I'm sorry.

MR. BROCK: Pursuant to the Court's scheduling order, the parties were required to exchange expert reports. On January 3rd, 2014, the plaintiff did do that disclosure, including -- can I excuse this witness or can the witness be excused while I'm making this argument? I think it -- as I argue, it will become apparent why I would ask this not be done in the presence of the witness.

THE COURT: Any objection to that, Mr. Pate?

MR. PATE: No objection, Your Honor.

THE COURT: Dr. Grubb, you need to be back here from the Court's perspective at 1:00. As you leave, you can quickly find out whether either lawyer would like you to be back sooner, but you can exit the courtroom now.

(Witness temporarily excused.)

THE COURT: Mr. Brock, while the witness is exiting -- and I don't think this is something you're saying, but there were numerous motions in limine filed in the case involving expert or opinion witnesses. Was any of what you're about to raise addressed in those motions?

MR. BROCK: Well, it relates to the motion in limine, but, Your Honor, I need to make this argument --

THE COURT: Just answer my question first before you tell me what you want to say. Was --

MR. BROCK: We --

THE COURT: Mr. Brock, my question is, is whatever

argument you're about to raise, was it raised in a motion in limine?

MR. BROCK: Correct. We --

THE COURT: Tell me what motion in limine it was raised in and what order I addressed it in.

MR. BROCK: Okay. This was the motion in limine -- and they're going to find me the reference. You want to wait for the reference before I speak further?

THE COURT: Well, you can tell me what the motion in limine was called.

MR. BROCK: It was a motion in limine including reference to language that would be related to punitive damage type context, such as the word "reckless" or "intentional." And Your Honor then -- your ruling essentially was, hey, this is more of a dispositive motion and it should have been raised, you know, as you -- by both sides, and you denied it as a motion in limine.

THE COURT: All right. Now I know what motion in limine you're talking about. I felt like your motion in limine was essentially asking me to rule that, as a matter of law, no evidence with respect to punitive damages could be raised by the plaintiff, and I think that my reasoning was set forth in the order that I issued about using a motion in limine to, in effect, ask for a dispositive ruling on all the evidence. So what now do you want to raise with me in conjunction with

that?

MR. BROCK: But in the context of our final pretrial conference, Your Court made it very clear to both parties that experts would not be allowed to get on the stand and give new opinions, and state, you know, that we'd be held to what our pretrial disclosures were and the depositions. My concern, and this is where if I waited until the --

THE COURT: Mr. Brock, you don't have to -- I'm not criticizing that you've asked for this now. I'm just trying to get to the heart of it so that I have time to rule on it, take a grand jury return, address all the other arrests that have been made while we're sitting in here, so --

MR. BROCK: So Dr. Grubb did a report on January 3rd, 2014, which is five pages long.

THE COURT: And as I mentioned to you at the final pretrial conference, I don't have complete copies of any of these reports. If anybody is going to be arguing somebody is going outside the scope of their report, surely somebody will provide me with a report. He issued a five-page report.

MR. BROCK: Right. And the plaintiffs did a disclosure describing what the testimony was going to be. Nowhere in his five-page report, nowhere in the expert disclosure, nowhere in the deposition, nowhere in the redirect examination by Mr. Miller at his deposition was the conduct ever described as reckless or intentional or gross or any words

that would be relative to -- that would support a claim for punitive damages.

My concern is that after a five-page report in great detail, a disclosure in great detail, and a deposition in great detail and a redirect examination, I do not want this witness to inadvertently or by prompting say words like "reckless" or "gross deviation" because that has never been stated in the disclosures, the report, the depositions, or redirect examination, and that is precisely my concern and why I raised it now so that the plaintiff's counsel --

THE COURT: All right. Let's break it down. Of course, those are legal terms under Tennessee law relevant in the case. Let's find out, Mr. Pate, is it your contention -- and if so, somebody please give me the report or disclosure -- that your witness has provided opinion testimony or disclosure that the conduct of Dr. Ball was reckless or intentional or -- what was --

MR. BROCK: Gross.

MR. PATE: I've got a copy of the report. It doesn't use the term "reckless" or "gross negligence." I have to double-check with our disclosure. I know that we've pled that this was grossly negligent and reckless behavior as part of our basis for a claim of punitive damages. I don't recall he was asked in his -- I don't believe he was asked specifically in his deposition by Mr. Brock whether or not he determined that

conduct --

THE COURT: And that's a great strategy because it's not in the report, it's not in the disclosure, and you don't inadvertently bring it up in a deposition --

MR. PATE: Well, I have to cross-reference it with our initial disclosure.

THE COURT: I tell you what I'm going to do. I don't feel like I'm getting as good a quick concise answer as I need, Mr. Pate, here and it may be what I'll do is I'm going to take a little break, check on the grand jury.

You're going to have to show me where he said it in a report or in a disclosure or in a deposition, because if he didn't, like I ruled already, there's not going to be any new surprise testimony. So why don't you talk about this. I don't even know that you're in dispute. Is that satisfactory to you?

MR. PATE: That's fine.

THE COURT: The fact that you pled it means you have opinion testimony supporting it, and I think that's what the -- there's no argument here that you failed to plead it. The argument that is you have not disclosed any expert testimony supporting it.

MR. PATE: I guess I can kind of understand that argument, but, you know, given the fact that we have pled it, they're -- it's not like they can come and say we'll be

surprised at these types of opinions. They understand we pled that this is grossly negligent and reckless behavior as part of our claims for punitive damages.

To turn around and then say, well, the words, the legal terms aren't actually put in the report or perhaps the disclosure -- and I'm not sure that's the case -- we're somehow unfairly prejudiced and surprised on account of that fact. I don't think that that holds any water, and I think that would be the concern that they would have.

THE COURT: Well, I envision that Mr. Brock's objection is that you are going to elicit -- I don't know what to do about this feedback. I'm not sure where it's coming from.

I believe what I was saying was I envision that the current objection being raised is that your expert is going to go outside the scope of his disclosures. Is that correct, Mr. Brock?

MR. BROCK: Yes, Your Honor.

THE COURT: And I've already ruled on that. That won't be allowed.

MR. PATE: And I'll represent to the Court and Mr. Brock, we're not offering Dr. Ball for the punitive, so we won't be eliciting any testimony --

THE COURT: I'll let you all talk about it some more in the break. If you find that you actually need further

guidance than you've already gotten from me in the motion in limine, I'll reconvene with you in about -- as soon as -- maybe five till 1:00 or something like that if need be, or ten till 1:00 if I can, whenever I can get back down here. I'm hopeful that, Mr. Pate, what I'm hearing you say and what I'm hearing Mr. Brock say, I'm not sure that you're not in basic agreement, but if you're not, you can perhaps be more prepared to show me where the disagreement lies.

Now, part of a motion in limine is it's always the duty of the lawyers not to attempt to circumvent the Court's ruling and advise the witnesses, so it's impossible, Mr. Brock, for you to actually prevail if Mr. Pate is not allowed to inform his witness that he should not offer any sort of opinions on these words. You wanted him out of here for the discussion, but I'm not sure that that behooves you in the long run because there has to be a way of communicating to him.

MR. BROCK: Your Honor, I have no objection to the witness being cautioned through counsel, even though he has taken the stand, and saying he cannot use words such as we've discussed that would suggest --

THE COURT: Well, he can offer opinions and that's what you all need to discuss, it sounds like, if in fact none of these opinions were disclosed in the report, I believe you said the depositions or the disclosures, so I think you'll have

plenty of time to discuss that if I let you go now and maybe even get a little bite for lunch. Is there anything else that we need to address?

MR. PATE: I don't believe so.

THE COURT: Let me address the issue of just scheduling and timing. I don't know if you anticipate Dr. Grubb will take as long as the rest of the afternoon and that's hard for you to say because your part will be perhaps even shorter than the cross, I don't know. Do you just have a bald estimate of what you think your direct will take? An hour, two hours?

MR. PATE: I'm thinking --

THE COURT: 30 minutes?

MR. PATE: I would expect at least two hours.

THE COURT: All right. I'm not holding you to this, but two hours for you and then about -- what do you think?

MR. BROCK: An equal measure or shorter.

THE COURT: So be prepared to have another witness. Yes. Just make sure you have something else planned in case we can get to it today.

MR. PATE: We've got the deposition of Dr. Johnson that we can play if we run out of time.

THE COURT: And we can stop that if we need to. You all have resolved your differences or not on that? If you have differences.

MR. MILLER: I believe we've resolved our differences.

THE COURT: Okay. I wasn't certain the last -- I mean, he's for certain, I think I got a notice he is not testifying live; correct?

MR. MILLER: Correct, we're playing a videotape. We just need -- we designated an hour and a half. They designated two and a half hours. We just need the same instruction about how both sides have designated so the jury doesn't think we're torturing them with four hours all by themselves.

THE COURT: If you're fine with the instruction I gave on Dr. Metcalfe, I mean, it will be a similar instruction.

MR. MILLER: In an ideal world, you'd tell them that defense designated two and a half, but you're not going to do that, so --

THE COURT: You're right. All right, we're adjourned.

(Court was recess for the lunch hour.)

THE COURT: All right. Well, let's go on the record, because it's long after the time that I -- we had set aside to resolve this, and the jury's ready to come back.

MR. MILLER: I think from plaintiff's perspective, Your Honor, we just want a little bit of clarification. We are not going to present Dr. Grubb to offer an expert opinion that Dr. Ball was grossly negligent, or for punitive damages.

That's a totally separate issue. And the argument's solely going to be based on the fact that Dr. Grubb saw all the FDA warnings, was aware the FDA told him not to do what he did. So we're not going to --

THE COURT: All right. And I don't know that I need to get into that, but--

Ms. Boyce, are you able to handle this aspect?

MS. BOYCE: Well, Your Honor, I prefer that Mr. Brock be here. I can tell you I know the key -- some of the key words, but -- we understand that Dr. Grubb will be referring to the FDA alert, but for him to use terminology such as reckless, I believe, is one of our issues in this. I prefer-- Mr. Brock should be here momentarily. But that is one of the issues, that he's not going to throw out words like reckless, which you find in the jury instructions for punitive damages.

MR. MILLER: It's not our intention, Your Honor, to elicit words like reckless or careless, but we haven't spoken with Dr. Grubb, we haven't met with him, and so I thought -- I understand Your Honor to say we can't elicit that opinion, but in terms of his terminology, you weren't ruling on that.

THE COURT: Well, I guess I'm sort of hampered in doing anything until Mr. Brock gets here.

(Brief pause.)

THE COURT: Mr. Brock, it's really not acceptable to come back after the time that we've set aside. We've got a

jury waiting. I hope that it won't happen again.

MR. BROCK: It won't.

THE COURT: And I'm assuming it was unavoidable.

So I think where we are-- Mr. Miller, let's start over so that Ms. Boyce doesn't have to repeat that to Mr. Brock.

MR. MILLER: Okay. So --

THE COURT: Wait. And where is Mr. Pate, because I don't know that-- He's the examiner. We need him in here.

MR. MILLER: I'll step out in the hall and get him.

THE COURT: And actually he's the one addressing this issue.

MR. MILLER: Okay.

(Brief pause.)

THE COURT: It happens.

MR. BROCK: I don't think I've ever been late before. I'm sorry.

(Brief pause.)

THE COURT: All right. Mr. Pate, this is your witness. This is your issue. I think we have everybody here.

MR. PATE: I mean, I think we've agreed we're not going to use the term they're worried about, reckless, grossly negligent, intentional, any of that.

THE COURT: And I think that the Court has ruled that experts cannot testify as to opinions that they didn't express

previously. So based on the representations that have been made to me, Dr. Grubb did not testify that it was a gross deviation of the standard of care, or a recklessness, and you're not going to attempt to elicit that testimony from him today, correct?

MR. PATE: That is correct.

THE COURT: And you are going to admonish him not to use those words, and we're going to move on. Now, whether or not -- and I will say this: Whether or not you can get to a jury on the issue without expert testimony is a completely different issue that I am not addressing right now, and did not address when I was asked in a motion in limine to rule that no evidence of that nature could come in, because I felt like that was asking for a dispositive motion, and I believe I expressed myself fully in that. But they are two separate questions, I believe, and I don't -- I don't hear any disagreement with that. But please talk to your witness. I'd like to get the jury in so we can get started.

MR. PATE: Okay. If I can have about 45 seconds, permission of the Court, I'll go ahead and provide the admonishment, and then we can --

THE COURT: Yes. Why don't we get him back on the witness stand before we have the jury come in, so he'll -- you know, we'll be in the same spot we were in when they took the break.

MR. PATE: Okay.

THE COURT: Take whatever time you need. Don't feel hurried, within reason.

MR. PATE: Okay.

(Brief pause.)

MR. PATE: Your Honor, can Dr. Grubb be permitted to approach the witness stand?

THE COURT: Yes. Please do.

(Brief pause.)

THE COURT: If you'll sit here, Dr. Grubb, once the jury gets in, we'll get started. I'll remind you you're under oath once the jury's back in here, and then we'll get started.

THE WITNESS: Okay.

THE COURT: Right there. And there's water in that pitcher.

(Brief pause.)

THE COURT: And while the jury's coming in, as I understand it, sounds like you might -- well, before they come in, sounds like you might be offering Dr. Johnson's testimony. I would like to be provided with a transcript so that I don't have to take as many notes, if both sides could accommodate that.

(The jury entered the courtroom, and the proceedings continued as follows:)

THE COURT: Welcome back. I hope you had a good

lunch.

A JUROR: Very nice.

THE COURT: All right. We will now be resuming the testimony of Dr. Grubb.

And I'll remind you you're under oath, so...

THE WITNESS: All right.

BY MR. PATE:

Q Are you ready to continue, Dr. Grubb?

A Yes.

Q Okay. Before we went to a lunch break, we were talking about some of your credentials. Do you recall that?

A Yes.

Q And one of the things that we established was that you are a licensed and board-certified anesthesiologist and pain management specialist?

A That's right.

Q Broadly speaking, before we get into some of the details of the case, can you just explain for the jury what it is that a pain management doctor is and does?

A Yes. It's a physician who focuses their practice on the treatment and evaluation of patients who have pain conditions of various types——chronic pain, meaning longstanding pain; acute pain, meaning relatively short duration of pain; cancer pain. A pain management doctor treats patients with all those complaints.

Q And one part-- Well, let me ask this: There are -- is it fair to say that there are numerous ways in which -- numerous approaches, modalities, if you will, that pain doctors utilize in treating patients?
A Yes.
Q And what are some of those, broadly speaking?
A Well, there are the ones most people think about, which would be medications. There are dozens of classes of medications that have been known to work for certain types of pain. There's also a category called interventional pain management modalities. That would be injection type procedures. As far as what a pain management doctor would prescribe would be also things that would be non-pharmacotherapy, such as physical therapy, devices such as TENS units, aqua therapy, massage therapy, some of the things that maybe we wouldn't perform in our office or setting.
Q And you mentioned that medications is one of the modalities that's employed?
A Yes.
Q And you also mentioned that there are all kinds of classes of medications?
A That's right.
Q Okay. Is one class of medications that can be used called opioid therapy?
A Yes.

Q What are opioids?
A Opioids are drugs that are generally derived from opiates from hundreds of years ago. Morphine would be the prototype opioid. Drugs have been developed since morphine was discovered that -- some of which are not naturally occurring opiates but are synthesized in a laboratory. Those still act in the same way on the nervous system. All of those class of medications that we call opioids act at a very specific receptor site in the nervous system, in the brain and the spinal cord, called the opioid receptor.
Q And, again, broadly speaking, Doctor, how many different kinds of opioid drugs are out there?
A Dozens of them.
Q Okay. What are some examples? You mentioned morphine. What are some other examples of opioid --
A Sure. There's oral opioids. Among oral opioids, the most common ones would be morphine, methadone, oxycodone, hydrocodone, codeine, other -- others than those, even, oxymorphone. There are-- Those are the main ones, I would say, of the oral ones.
There are other ones that are delivered in other routes of administration, intravenous opioids, which would be -- morphine can be used intravenously, Demerol, fentanyl, very common IV opioid.
Q When you say "IV, intravenously," you're talking

about administration of the opioid medication directly into the bloodstream through a syringe or some other form of intravenous administration?

A That's right, obviously not something someone would do at home, at least not legally, and that would be a hospital or a clinic environment where someone would get sys- -- get IV intravenous opioids through that mechanism.

And then there's transdermal opioids. There are a couple of those on the market, fentanyl being the most common one. I believe there's one called the Butrans patch that's also an opioid that's transdermally administered.

Q And some -- is it fair to say some opioids are long-acting and some are short-acting?

A Yes.

Q Okay. And what's the difference between the two?

A Well, that's an important difference, and that is probably the most common differentiation that pain physicians would use with opioids.

Short-acting opioids, as the name sounds, would go away very quickly in the bloodstream. Those are used frequently for pain that changes over time. Someone has a knee replacement, let's say, and when they're getting up ready to walk around and it's going to hurt, they might want to take a short-acting opioid to get them through that painful time, certain activities.

A long-acting opioid is predominantly prescribed by pain medicine specialists. There are some primary care doctors who also feel comfortable prescribing those. Those are a little different category, a little bit more risk associated with them. Those are opioids that stay in the bloodstream, intended to stay in the bloodstream at a constant amount. For oral opioids, that would need to be a special type of drug or preparation that would last maybe 12 hours, so that then it can be taken twice a day. There were some medications on the market trying to make them last 24 hours, so that if you take it every 12 hours, if that's that particular drug, or 24 hours, around the clock that will provide the same concentration in the blood on a continuous basis. So that's the big difference between long-acting and short-acting.

Q And one of the major issues in this case, obviously, is fentanyl in transdermal form with the fentanyl patch. That preparation, is that considered to be short-acting or long-acting?

A That would be very long acting, I guess considered the longest acting, because it's -- the single patch that you keep on the skin is intended to deliver a constant flow of medication in the body for 72 hours, as opposed to the pill form opioids that would need to be redosed, obviously, much more often than 72 hours.

Q And by "redosed," do you mean like, for instance, a pill preparation, continually taking the pills in order to maintain the opioid in the bloodstream?
A That's correct. If you don't take the next dose of a pill, then obviously the blood level would go down, whereas the fentanyl patch is going to have the same -- the same, generally, concentration in the bloodstream for a full 72-hour period.
Q And we talked about some of the different kinds of opioids, but do opioid medications themselves, do they differ from one another in terms of their potency?
A Yes.
Q Okay. And, again, can you just explain to the jury the concept of potency? What does that mean in the broad framework of what we're talking about with opioid medications?
A Well, it's a simple concept in that it's a relative term, potency, related to the actual amount of the drug to achieve a certain therapeutic effect, in this case pain relief. So, in other words, a very high potency drug, only a tiny amount of the drug, milligrams or micrograms, is necessary to reach that target, that goal; whereas, another drug that would be considered lower potency would require a whole lot more of that medication to get the same pain-relieving effect as the higher potency one that would take a tiny amount. So that's -- it's a general term that is

a relative term between drugs.
Q Fentanyl, of course, is an opioid drug?
A Yes.
Q And among all the different opioid medications out there, where does fentanyl fall on that potency scale, if you will?
A It -- it's, I would say, the most potent. I don't know of any other drug that's prescribed on an outpatient basis that would be more potent. It's the most potent opioid outside of other medications only used in an IV form.
Q Okay. And when you say "an outpatient setting," you're talking about what?
A Prescribed, that you could pick up at the pharmacy, at-- I guess a better way to say it is, fentanyl would be the most potent opioid that one could get at an outpatient pharmacy.
Q Fentanyl is a Schedule II narcotic. Is that right?
A Yes.
Q Okay. And what does that mean, to be a Schedule II narcotic?
A Well, this idea of scheduling a narcotic is something that the Drug Enforcement Administration has done over the years on the basis of how addictive certain opioids are and how likely they are to be sold on the street in an illegal fashion, like heroin. Schedule II is the highest --

is the highest risk, if you will, rating of commonly prescribed medications. Morphine would be on that list. Demerol is on the list. Oxycodone is on that list of Schedule II.

Lower schedules, such as Schedule III, Schedule IV, are still addictive substances that people might even sell on the street, but they're not as addictive, and therefore they're not as dangerous to be prescribed.

Q Do anesthesiologists such as yourself use fentanyl in your anesthesia practice?

A Yes.

Q Okay. And how so?

A Well, it's our most common IV opioid that we would use during surgery to treat someone's pain such that when they wake up from surgery they're not hurting. We use it in over 90 percent of operations at our hospital.

Q Okay. And with respect to fentanyl that's used in the outpatient setting, what is the most -- and by that, we already discussed that you can go and take home from the pharmacy, what is the most common preparation of fentanyl in that context?

A Well, the only -- the only safe ways to prescribe fentanyl outside of a hospital setting would be the transdermal patch, the fentanyl patch. There are some preparations of fentanyl that are a type of oral -- they're

actually transmitted through the mucosal lining of the mouth, so there's a little pill that's called Fentora; it's a fentanyl that can go under the tongue. There's a little lollipop fentanyl preparation called Actiq, for cancer pain. That's the only way I'm aware of that fentanyl is used. And it's -- that's a totally different -- it is, should, for that matter, be almost considered another drug than what we give IV. The way the body handles fentanyl through a vein is a lot different than the way it many handles fentanyl or metabolizes fentanyl through the skin, for example.

Q In your career have you prescribed fentanyl in transdermal form, again, fentanyl patches, to your patients in your practice?

A Yes.

Q If you were to ballpark it for me, approximately how many different patients have you prescribed fentanyl patches to during your career?

A Just ballpark, maybe about 200 patients, total.

Q Okay. And we've touched on this a little bit, but could you explain to the jury, in terms of how the fentanyl goes from the patch and into the bloodstream and acts on the nervous system, how does that process work once a patient applies a patch to the body?

A Well, there's proprietary type of technology that's used in these patches that can include fentanyl in either a

matrix form or a little reservoir within the patch that then, as you might expect, takes a while, takes a few hours, many hours in most cases, to start working, because it has to work its way through the skin and get absorbed into the bloodstream.

The idea there is that it's a slow absorption. Unlike using it in an intravenous line, which would be an immediate effect of the fentanyl, the patch can deliver this real slow supply of opioid to the body, such that it's not an immediate effect but over a period of 16 to 36 hours. It reaches a peak usually in the thirty-something-hour range in the bloodstream. And as long as you keep changing that patch every 72 hours, the bloodstream reaches what it calls a steady state of the fentanyl drug. What that really means is that-- The fentanyl, due to its nature, stays in fat and muscle tissue more than it even stays in the bloodstream, so it serves as this reservoir of fentanyl drug in the body, and it is slowly getting released back into the bloodstream from the fat and the other tissues, so that if you keep taking it every 72 hours, you can get a pretty constant blood level of the fentanyl, which is what prescribers want when they prescribe it for someone that they want to have around-the-clock, 24 hours a day exactly the same amount of opioid in their system.

Q And following up on that, why -- or what clinical presentation would a patient have to have, again, generally

speaking, that would occasion a physician's desire to maintain a constant level of fentanyl in the blood?

A Well, the original purpose of long-acting opioids would be cancer pain. A lot of cancers, they spread to the bone, it's a very constant deep ache that occurs 24 hours a day, even in the middle of the night. And so those patients were very happy when long-acting opioids came on the market and different options came out for them.

In the past 20 or so years, we've started using those for non-cancer pain but pain that we still would consider somewhat terminal. And what I mean by that is, an example would be someone that's had multiple back operations. I think we've all known people that have had back surgery, and sometimes it doesn't work. We call that "failed back syndrome." We tell those folks, "Look, you're going to be needing this pain medicine probably the rest of your life. Your back just is worn out or degenerated. And the best that we can come up with is a long-acting opioid that's going to take care of your pain on an around-the-clock basis."

Q Are there instructions that come with every box of fentanyl patches that a patient picks up from the pharmacy?

A Yes.

Q And what is that -- what are those instructions called?

A It's called the package insert.

Q Okay. And we'll talk about the package insert in some more detail, but can you again just describe generally for the jury what the package insert is, what its purpose is, the type of information that it contains?
A Well, most of us have seen this package insert. It comes with all the medications that we pick up from -- from the pharmacy, all prescription medications. And the vast majority of the information in a package insert is for the physician. It uses a lot of technical medical terms that you would expect a physician to know. Most of them also have a little portion that's directed more to the patient, so that if there are certain issues with a particular medication, what not to take it with, whether you can consume alcohol with it, those type things certainly would be for the patient to know, too. So I think they're intended to be read by both the physician and the patient, at least for the patient the parts that are directed more to the patient.
Q Okay. And is the package insert specifically approved by the federal Food and Drug Administration?
A Yes.
Q Does the full prescribing information of the package insert contain -- for fentanyl packages contain what's called a black box warning?
A Yes.
Q What are black box warnings?

A Well, black box warnings are a different category within the package insert, that's usually at the very beginning. A handful of medications have these black box warnings, and it's intended for the FDA to alert the prescriber of specific concerns that are more than just the typical drug that may not have as much danger. And always a black box warning has to do with dangers, not as much how -- information about the drug and what it's made of and how it works, but when not to prescribe it, what could happen if you prescribe it in the wrong manner. Those are contained in a black box warning.

Q I'm going to show you, Doctor-- This is Exhibit J-12, a copy of the Duragesic package insert. And if I can get the first page. Can you see that on your screen, Doctor?

A Yes.

Q Okay. I'm not pointing to any specific content, but you see on the left-hand column there's a section that is surrounded by -- quite simply is a black box.

A Correct.

Q And is that -- when you referred to earlier the black box warnings for fentanyl, is the information contained within this box, is that the black box warnings that you were referring to earlier?

A Yes. This is the black box warning for the fentanyl patch.

Q Okay. With that -- with all that information, Doctor, I want to talk a little bit about Dr. Ball's treatment of Donald Guthrie. Have you reviewed Dr. Ball's records pertaining to the care and treatment that he and his staff provided to Donald Guthrie?
A Yes.
Q When-- Do you have a copy of the records with you?
A Yes, I do.
Q Okay. When did Donald Guthrie first present to Dr. Ball's office?
A December 7th, 2009.
Q Okay. And I'll refer you to Page 15 of Exhibit J-4. There is a notation made during this initial visit regarding Donald Guthrie's chief complaint. What was his chief complaint on this initial presentation?
A Left knee pain.
Q And according to the records that you've reviewed, Doctor, when did that knee pain start, according to Dr. Ball's records?
A It started on October 17th, 2009.
Q And how did that knee pain start, again, according to Dr. Ball's records?
A It says that Mr. Guthrie was sitting at his desk and all of a sudden he had unbearable pain in his left knee.
Q And what was the etiology of that knee pain, what

was that ultimately determined to be?
A A medial meniscal tear.
Q Can you describe that in English for us? What is a medial meniscal tear?
A Sure. There's some little cushion type things in the knee that are called menisci, a meniscus. There's one on the inside of the knee. There's one on the outside of the knee. And in Mr. Guthrie's case, he had a tear in that little cartilage cushion, buffer. It's very, very common. I've had one myself. It's-- The one on the inside is called the medial meniscus. So he had a medial meniscus tear.
Q And you said you've had some personal experience with this as well. What happened in your case?
A Well, incidentally it was exactly the same. I was sitting at a meeting with my partners at the hospital, and as soon as I got up from sitting for a long period of time, it was bad, it was like 10-out-of-10 pain. Maybe I'm just a wimp with it, and I probably am, but it was really bad. And it went on for a month or two, and finally I convinced the orthopedic surgeon to at least take a look in the operating room. And he found the tear, and I've been pain-free in that knee ever since. But it's very common.
Q During this initial December 7, 2009, presentation, there were some descriptions that Mr. Guthrie gave to Dr. Ball's office about the knee pain itself. Is that right?

A That's right.
Q Okay. And if you look at this pain evaluation, what were some of the descriptions that he gave regarding the nature of this knee pain?
A Well, he said the pain was intermittent in nature. He described it -- the characteristics of it were sharp and throbbing, and --
Q Are you reading -- again, are you reading from this portion here, Doctor, regarding description of the intermittent pain?
A Yes. "The pain is intermittent. Pain description, sharp and throbbing, worsened by lying down and standing."
Q As a pain management specialist, do you appreciate the distinction between acute pain and chronic pain?
A Yes.
Q The type of pain that Donald Guthrie is describing in his knee as reflected in these records, is that consistent with an acute pain condition, or a chronic pain condition?
A Acute pain.
Q Going back to Exhibit J-12, the package insert, I want to draw your attention, Doctor, to some specific portions of the black box. And I want to start with the underlaying portion that begins with the words "Because serious." Do you see that?
A Yes.

Q Okay. Can you read that, Doctor, just the underlined portion?
A "Because serious or life-threatening hypoventilation could occur, Duragesic fentanyl transdermal system is contraindicated."
Q And then there's a number of bullet points below that, right?
A That's correct.
Q And what do those bullet points reflect?
A They reflect the conditions for which the fentanyl patch is contraindicated and shouldn't be prescribed due to the risk of life-threatening hypoventilation.
Q Okay. Again, just for the benefit -- for those of us who don't know, what does it mean for a drug to be contraindicated?
A It's -- means that it should not be used.
Q Okay. We talked earlier about the prescription of Donald's knee pain as being intermittent. Is that right?
A That's right.
Q Do you see down here at the bottom -- what does that say about the prescription of fentanyl to patients with intermittent pain?
A That it's contraindicated in the management of intermittent pain.
Q And we'll talk some more about that in the context

of acute pain, but why was it, or why is it, in your opinion, that the pain condition that Donald Guthrie was describing to Dr. Ball's office as of December 7 was an acute pain condition?

A Well, it was due to an injury. That's the definition of acute pain, is, it is the pain that results from some sort of trauma, whether it be surgery, like an incision, an ankle sprain, some sort of injury. And in this case Mr. Guthrie had an injury of his knee.

Q Let me take you to Page 16 of Dr. Ball's records, Exhibit J-4. And for the benefit of myself and hopefully you as well, Doctor, there are some indications about Donald's weight and size that are documented underneath the "Objective" portion of this report. Do you see that?

A Yes.

Q Okay. And how much did Don -- Donald Guthrie weigh during this initial visit, according to this record?

A 318 pounds.

Q And his height was what?

A 77 inches.

Q And what was his body mass index indicated to be?

A About 38.

Q And where would that put Mr. Guthrie on the obesity scale?

A Well, it would be significantly overweight, obese.

And with other medical conditions, such as his diabetes, it would make it be considered morbid obesity.

Q And what is morbid obesity?

A Morbid obesity-- There are a number of recommendations as far as the actual number for BMI. Most -- most literature says if it's over 40 BMI, then that's morbid obesity just based on the BMI; if it's over 35 but with other health problems that could be associated with obesity——high blood pressure, heart disease, diabetes——then that would make it morbid obesity on the basis of having these other medical problems associated with the high BMI.

Q Based on your review of Mr. Guthrie's medical history, did he have a history of smoking?

A Yes.

Q And, again, Page 15 of Dr. Ball's records documenting the December 7 visit, do those records note that Mr. Guthrie had any respiratory conditions?

A Yes. It says, "Emphysema/COPD."

Q And what is COPD?

A Chronic obstructive pulmonary disease.

Q Can you elaborate on what that means, again for those of us who don't know?

A Sure. It's a broad term to mean that the air flow is obstructed in some way, and that can be from a number of different diseases——asthma, emphysema. Those are the two most

common ones. It's just the term that is sort of the umbrella term to cover all of these common pulmonary diseases.

Q Can COPD cause shortness of breath?

A Yes.

Q And looking at Page 16 of Dr. Ball's records, again, for the December 7th visit, what did Mr. Guthrie communicate regarding his respiratory condition?

A He said he had shortness of breath.

Q Are there risks, Doctor, that are associated with prescribing long-acting opioids like transdermal fentanyl to people with conditions like obesity or COPD?

A Yes. It's widely accepted that those conditions——obesity, COPD——increase the risk of respiratory depression.

Q Did Mr. Guthrie also report that he had some difficulty sleeping, during this initial December 7 visit?

A Yes.

Q Okay. And as a pain management specialist, what is the significance -- if a patient reports difficulty sleeping, what significance does that have to you with respect to a patient that has the clinical profile of Donald Guthrie that we've been going through?

A Well, in this case it could be any number of reasons someone would have sleep difficulty, insomnia and those kind of things. I think in Donald Guthrie's case he had some risk

factors for having not really good breathing during his sleep, due to the morbid obesity and the COPD, so that that poses a higher risk. To a pain specialist, we're used to seeing people that are in that category, and we know that we have to be a lot more careful when it comes to sedative medications.

Q Aside from the knee pain, were there any other pain conditions that were diagnosed by Dr. Ball's office?

A Not at that visit.

Q Well, let's go ahead and look at one more page. Page 17 there is a reference to -- that I've highlighted here, "RSD symptoms." Do you see that?

A Yes.

Q Okay. And maybe you can read the first two words and, I guess, the rest of the highlighted portion there for us.

A "RSD symptoms, cutaneous allodynia across dorsal surface of left and medial aspect of left knee. No hyperhidrosis."

Q What is cutaneous allodynia? Am I pronouncing that right?

A That's right.

Q What does that mean?

A That's a descriptor of a painful response that someone might have to a non-painful stimulus. So even just lightly brushing your fingers across this particular painful

part of the body would elicit pain when that's obviously not a normal thing. That's what allodynia means.

Q There's also a reference to a term called hyperhidrosis. I didn't know what that meant until very recently. Why don't you tell us.

A Well, it's common with this reflex sympathetic dystrophy diagnosis. It's very common, with this pain condition, to affect the sweat glands. The specific types of neurons that are involved in that rare pain condition involve the sweat glands, the temperature sensation. So hyperhidrosis is too much sweating relative to the other limbs. So you would want to compare one knee to the other in this case, does this knee have more sweating than the other knee, does this knee have a warm or a coolness compared to the other knee. Those are things that are known to be part of the diagnosis of this RSD condition.

Q Okay. And we'll talk about RSD a little bit more in a little while, but what was the plan that Dr. Ball initiated with respect to Mr. Guthrie after this first December 7 visit?

A Well, he recommended that the patient undergo a left lumbar sympathetic block, and gave Mr. Guthrie a prescription for an oxycodone product, Percocet.

Q What are left lumbar sympathetic blocks? Can you tell the jury what those are?

A Sure. As I was mentioning before about the type of

neurons involved, those neurons don't -- you don't get to them in the spinal cord, like you might for someone with, say, sciatica symptoms down a leg could be a specific nerve. This is a different type of neuron, a different type of nerve, if you will, called a sympathetic nerve, and so it's a very different place in the spine where -- where a pain management doctor would put a needle to inject a local anesthetic around this -- this sympathetic -- it's called a sympathetic chain. It's a chain of neurons that run right in front of the spine. And ideally he wants to numb just those nerves, not the nerves that make you numb in places, different -- it's a different type of nerve, so that you can diagnose, first of all, that -- if the pain goes away right away, then maybe that would indicate this is RSD; if the pain doesn't go away, then maybe it would be a pain of a different type of nerve. That's the purpose and the -- the procedure itself.

Q You also mentioned the plan to initiate the prescription for the Percocet --

A Yes.

Q -- correct? Okay. Percocet is what kind of drug? What's the preparation of it?

A It's an oral opioid, Schedule II.

Q Okay. And it's a combination of drugs, as I understand?

A Yes.

Q All right. What's the combination? What are the two drugs that are combined to make a Percocet tablet?
A Oxycodone and acetaminophen.
Q Oxycodone is an opioid drug, right?
A Yes.
Q What is acetaminophen?
A It's an a non-opioid pain reliever.
Q Okay. And is Percocet at the dosage that was prescribed by Dr. Ball, is that short-acting or long-acting?
A That's short-acting.
Q And how much Percocet was Mr. Guthrie prescribed?
A The 7.5-milligram dosage. I believe he gave 90 at that visit.
Q Okay. And we'll look at Page 18 of Dr. Ball's records. Again, we're still on the December 7 visit. And we see there the Percocets, and the preparation is 500/7.5 milligrams. And, again, can you just say -- tell the jury what that refers to, those numbers?
A The 7.5-milligram number is the milligrams of the oxycodone part, which is the opioid part.
Q And it says, "One tablet oral tid," and there's a parenthetical. What does that mean?
A That means to take it, as needed, one tablet three times a day.
Q And if Donald Guthrie had taken three tablets a day,

how much oxycodone would he have been consuming on a daily basis, approximately?

A It would be three times 7.5, which is 22.5 milligrams per day.

Q All right. How many lumbar injections did -- lumbar sympathetic blocks did Mr. Guthrie have, according to the records?

A Three.

Q So the Percocets were prescribed on December 7, and Mr. Guthrie returned to Dr. Ball's office-- Well, strike that. About two months after Donald Guthrie's visit -- initial visit to Dr. Ball on December 7th, he returned to Dr. Ball's office with the remaining Percocets that had been prescribed. Do you recall the date of that visit?

A January 6th.

Q Well, this was two months after.

A Oh, February 4th, I believe that was.

Q Right. So we're on the February 4th visit. And Mr. Guthrie reported his experience with the Percocets during that visit, did he not?

A Yes.

Q Okay. And I'm on Page 26 of Dr. Ball's records. Now we're on the February 4th visit, approximately two months after the initial visit. And Mr. Guthrie describes his reaction to the use of the Percocet. What was that

description?
A It says he doesn't take the Percocet much due to upset stomach.
Q Did he bring some Percocet pills that he was prescribed on December 7th with him to this visit?
A Yes. Those were the rules that he signed on with Dr. Ball's office, that he would bring all remaining medications. And so he had the Percocet pills left over that he brought.
Q And while we're on that, what's the purpose -- what's the purpose of that; as a pain management specialist, if you require your patients to bring medications back to you, what's the reasons for doing that?
A Well, they're very addictive substances, obviously, since the Drug Enforcement Administration is very involved. And they can be sold on the street, and that's bad for the whole community. But particularly the addiction side of things, which would apply to that specific patient's health, we would want to know if they're taking a little more than they're supposed to. So if they should have, based on the dates, say, 20 left over, and they come and they don't have any left over, then that's a sign they've taken too many, and that might be a sign of an addiction developing to the opioid.
Q Based on your comprehensive review of the medical records in this case, is there any indication that Mr. Guthrie

exhibited any of those characteristics, those concerning characteristics about addiction or abuse of any of the opioid medications that he was prescribed?

A No, not at all.

Q Okay. And so let's go to-- We talked about the Percocets that were prescribed on December 7. Let's go to Page 27 of the --

THE COURT: Are you about to go to a new page?

MR. PATE: Yes, Your Honor.

THE COURT: I'm going to apologize to everybody in here about having to interrupt so soon after our lunch break, but there is a matter that I need to attend to with respect to the grand jury, and so -- it should not take me more than five minutes, and I think rather than have you sit through it, which you're welcome to do because there's an open session of court, but I suspect you'd rather take a little break. So if you don't mind, please stay nearby. It shouldn't take me more than five minutes.

Dr. Guthrie, you can stay right where you are, as can all the lawyers.

(Brief recess.)

THE COURT: Could you get the jury.

Doctor, I just want to remind you you remain under oath.

Mr. Pate?

BY MR. PATE:
Q Are you ready to proceed, Doctor?
A Yes.
Q Okay. Before our brief break, we were talking about the fact that Mr. Guthrie had received a prescription on December 7, his first visit with Dr. Ball, for the Percocet tablets at seven-point-five milligram oxycodone doses. Right?
A That's right.
Q Okay. And fast forward two months. We're at the February 4th visit, and Mr. Guthrie goes in with his leftover Percocet pills. Is that right?
A That's right.
Q Okay. And going to Page 27 of Dr. Ball's records, again Exhibit J-4, there was a medication count that was actually -- that was actually done. And it's highlighted in this portion of the note. Is that right?
A That's right.
Q Okay. And what does that medication count reveal?
A That he brought back sixty-three of the ninety oxycodone seven-point-five tablets, which means he took twenty-seven.
Q Twenty-seven Percocet tablets over the course of approximately two months.
A That's right.

Q And, if you were to average -- average it -- because nobody knows exactly how many he would have taken on any given day. If you were to average it out over that two-month period, how much pills per day of Percocet?
A Well, it would be less that half a pill per day. So he had sixty. Using twenty-seven, that's roughly a half a pill a day or just under a half a pill a day.
Q We've established that each pill had seven-and-a-half milligrams of oxycodone. Right?
A That's right.
Q And so, again, averaging it out over those two months, what was his daily consumption of oxycodone during that time period?
A About three-and-a-half milligrams.
Q What does the prescription information, the package insert, say is the minimum amount of oxycodone that a patient needs to consume to be eligible for the twenty-five microgram patch?
A That's thirty milligrams per day average for a week or longer.
Q Okay. And, in this case, utilizing that average, we're at how many milligrams per day?
A Three-point-five milligrams per day.
Q What did Dr. Ball and his physician assistant do in response to Mr. Guthrie's complaints about the Percocet?

A They changed -- they discontinued the Percocet prescription and wrote a new prescription for MS Contin, fifteen-milligram tablets, which is a longer acting morphine medication.
Q And, going to Page 28 of Dr. Ball's records again, February 4, is this the new prescription that you're referring to, Doctor?
A Yes. Fifteen milligrams, one tablet, twice a day, for seven days.
Q Okay. And the MS Contin is -- is what kind of drug again?
A It's a long-acting opioid.
Q It's morphine -- right? -- oral morphine.
A That's right.
Q And the dose is initially indicated in this note as a fifteen-milligram tablet with instructions to take twice a day. Right?
A That's right.
Q And so the total morphine intake -- after the Percocet's discontinued now -- the total morphine intake, according to these instructions would be how much on a daily basis?
A That would be thirty milligrams a day.
Q Was this dose of oral morphine subsequently increased by Dr. Ball's office?

A Yes.
Q And when was that?
A Approximately a week later, it was increased -- or a few days later -- increased to thirty milligrams twice a day.
Q And that was per that telephone order on February 8. Is that right?
A That's correct.
Q And it was increased to -- what was the dosage increased to?
A Thirty milligrams, twice a day. It was doubled.
Q And so the daily intake, per that instruction, would have been how much per day?
A That would be sixty milligrams of morphine per day.
Q Okay. And why was his dosage increased?
A I believe Mr. Guthrie called and said that the fifteen-milligram dose twice a day was not working well.
Q Okay. Mr. Guthrie then had another visit with Dr. Ball's office. What was the date of his next office visit?
A I believe March 4th.
Q Okay. And I'm now, Doctor, on Page 32 of Dr. Ball's records; and you can refer to the highlighted portions or other portions if you need to. But what did Mr. Guthrie report was his experience with use of the oral morphine, or the MS Contin?
A It -- he says that it was keeping him awake, it was

causing itching.
Q And it goes on to report that he stopped taking it at a certain point. What do the notes indicate there?
A He stopped taking it after he had a seizure and went to the emergency room. The emergency room doctors recommended that he stop the MS Contin medication.
Q Okay. And what was that date of that seizure? Do you recall?
A It would have been only a couple of days after getting -- starting his MS Contin. I don't recall the exact date.
Q No reason to dispute it was on February 21st.
A Yes.
Q Okay. So there was -- again, there was a medication count that was done on this March 4 visit. Right?
A That's right.
Q And, looking at Page 33 of Dr. Ball's records, does the medication count that was done on March 4 indicate how many MS Contin tablets, or oral morphine tablets, were remaining from the thirty-milligram dose which was dispensed on February 8th or February 9th?
A Almost all of the original sixty were remaining. Fifty-eight were remaining.
Q Okay. And it indicates that the dispensed amount on February 9 was how many?

A Sixty tablets.
Q Okay. So that would have been only two tablets that were used between, according to this record, February 9 and March 4?
A That's correct.
Q Okay. Is there anything to suggest -- in any of the records you reviewed, including Dr. Ball's records, is there anything to suggest that Donald Guthrie consumed any opioid medications whatsoever between the time of his seizure on February 21st and the date of this visit, March 4?
A No. There's no evidence of any opioid consumption at all after the seizure on the 21st of February.
Q And that would have been an eleven-day -- approximately an eleven-day period?
A Yes.
Q Earlier, we -- we noted the reports on Page 32. And, again, we're still on the March 4 visit. You noted in the reports that the morphine was keeping him awake anyway and was also causing the itching. You referred to that earlier. Right?
A Yes.
Q Is the itching, the report of itching, is that clinically significant to you?
A Yes.
Q Okay. And why?

A Well, itching is a common side effect of opioid medications; and it's well-accepted that the first effect you should get from an opioid, as far as the dose -- as you're increasing the dose, the first effect would be -- well, technically, constipation. That's another side effect, and that occurs at very low doses.

The next effect you would get would be pain relief. Above that concentration where you're getting pin relief, it would be just more side effects, such as itching, nausea, super-sleepy symptoms.

And, in this case, whenever we see someone that has itching, we take note that that might mean that we've reached a top level dose for that medication, certainly to the point where they're having side effects. We then could use the same medication, just decrease the dose, to reach that point where it effectively treats the pain but not get the itching. So the itching is an important side effect.

Q And you refer to side effects. Is there another way you can term side effects to be entering into the realm of toxicity?

A Well, it would be a relative term, getting into the -- "toxic" technically means the level above your therapeutic, or treatment, level. So anything above what's causing good pain relief, now getting into side effects, would be entering the range of a toxic level of fentanyl. Or excuse me.

Morphine in this case.
Q No indication, though, that there was any morphine that was being consumed by Mr. Guthrie for that eleven-day period prior to this March 4 visit.
A That's correct.
Q All right. So Dr. Ball and his physician assistant replaced the MS Contin with another opioid medication, did they not?
A Yes.
Q And what was the medication the morphine was replaced with?
A The fifty-microgram fentanyl patch, as well as an oral Dilaudid medication.
Q All right. And this is Page 35 of Dr. Ball's records. Do those notations that I've highlighted there denote the two opioid medications that Donald Guthrie was prescribed on that date?
A Yes.
Q What were the instructions for the use of the fifty-microgram-per-hour patch?
A To use one patch every seventy-two hours.
Q We talked a little bit about that earlier. Right? You put the patch on. The medication is absorbed. You pull it off after three days and stick on another one.
A That's correct.

Q The Dilaudid, what kind of medication is Dilaudid.
A It's a relatively potential opioid as well.
Q Okay. And what's the generic name?
A Hydromorphone.
Q And what were the instructions for the use of the Dilaudid?
A That -- to take one tablet, every six hours, as needed.
Q Have you heard the term "breakthrough pain"?
A Yes.
Q What is breakthrough pain in the context that we're talking about here?
A Well, in general, breakthrough pain refers to that extra pain over and above the constant pain that someone with chronic pain would have, such as with certain activities, like going out to walk the dog might bring on pain even more than the baseline pain. So you give an extra medication, that's a short-acting opioid, for people to take as needed for those extra episodes of flare-ups, if you will.
Q That is the pain that, I guess you could say, breaks through the relief you would get from the patch.
A That's correct.
Q And, in this case, that would have been the hydromorphone, or the Dilaudid.
A Yes. That's right.

Q What was the next office visit? What was the date of the next office visit that Donald Guthrie had at Dr. Ball's office?
A March 18th.
Q And was this the last visit that Mr. Guthrie had to Dr. Ball's office prior to his death?
A Yes.
Q And, during this March 18 visit, Doctor, did Mr. Guthrie report the effects of his latest medication regimen -- that is, the fifty-microgram fentanyl patch and the hydromorphone, or Dilaudid?
A Yes. He says --
Q And I'll referring you, Doctor, just for the benefit of the rest of us, to Page 37 of Dr. Ball's records. What, in the "Pain Followup" portion of this report -- what does Don indicate was his experience with these -- this new opioid medication regimen -- that is, the fifty-microgram patch and the hydromorphone?
A It simply just says that, since his last visit, his activity level has worsened. His mood has worsened. His quality of sleep has worsened. The pain is continuous. The pain is gnawing and aching. Same pain complaints, relieved by nothing. Numeric pain score is an eight out of the scale of one to ten, which is what it was his last visit. Describes difficulty falling asleep, difficulty staying asleep. The

current medication regimen works poorly.
Q Incidentally, do you recall what Mr. Guthrie's pain score was on the one-to-ten scale during his initial visit with Dr. Ball on December 7th?
A Yes.
Q What was it?
A That was a five.
Q So, after trying the Percocet, the -- he walks -- Donald Guthrie walks in with a pain score of five after the Percocet; the morphine, at fifteen milligrams, twice a day, to thirty milligrams twice a day; a fifty-microgram patch with hydromorphone on top of that, and his pain's gone from a five to an eight?
A Yes.
Q How many patches -- well, let me start by asking this. Was there a medication count again that was performed on this March 18 visit?
A Yes, there was.
Q And, on Page 38 of Dr. Ball's records, again March 18, the last visit, what does the medication count reveal about the number of fifty-microgram fentanyl patches that were remaining from his previous prescription?
A Two patches out of the five.
Q And how much Dilaudid did Don use during that two-week period for breakthrough pain?

A About nineteen. And I think, in another place, it says one fell in the trash on that visit, so eighteen.
Q Was there also reports of itching reported to Dr. Ball during this March 18 visit, this last visit?
A Yes. He did report itching as a medication side effect, as well as fatigue.
Q And, again, is this -- are these reports of itching and fatigue, are those clinically significant to you in looking at the big picture of Mr. Guthrie's treatment?
A Yes.
Q And why is that?
A Well, again, fentanyl, like any opioid, can cause itching, particularly the higher doses, as well as fatigue. Particularly, if someone isn't sleeping very well, they're going to have fatigue as well.
Q So what adjustments did Dr. Ball and his physician assistant make to Mr. Guthrie's medication regimen at this point?
A They refilled the Dilaudid prescription; and they increased the Duragesic patch, the fentanyl patch, to the seventy-five-microgram dose.
Q Is that reflected here on Page 39 of Dr. Ball's records, the discontinuation of the fifty and the initiation of the seventy-five-microgram-per-hour patch?
A Yes, that's right.

Q And, again, instructions for use of the seventy-five patch were?
A Put it on for seventy-two hours at a time and change it every seventy-two hours.
Q Did Mr. Guthrie have any other visits with Dr. Ball after this day, March 18, 2010?
A No.
Q So we've gone through Mr. Guthrie's medical treatment with Dr. Ball and his office staff, and we've talked a little bit about fentanyl patches in general terms, and we have talked about the black-box warning. Right?
A Right.
Q I'm going to ask you some more questions about that now, Doctor. I'm going to start by asking -- well, I'm not sure I've asked this question, but how many different doses of fentanyl patches are there?
A The smallest dose is twelve micrograms, twenty-five micrograms, fifty micrograms, a hundred -- seventy-five micrograms and a hundred, for five doses of the fentanyl patch.
Q Is it fair to say -- a fifty-microgram is kind of the middle of the pack as far as the dosing is concerned. Right?
A Yes.
Q Seventy-five is kind of on the higher end?

A Yes.
Q Not the maximum, but there's only one next step.
A Yes.
Q And one of the things that's come up and I want to talk with you about now is this issue of opioid tolerance. As a clinician, are you familiar with the concept of opioid tolerance?
A Yes.
Q Can you explain that to the jury? What is op -- what does that concept mean, opioid tolerance?
A Sure. Well, I mentioned before about this receptor site that's in the nervous system, the spinal cord and the brain. And, the more that that receptor is bombarded, if you will, with an opioid drug that's activated, particularly in a constant manner, it's going to get used to it and not give you the desired effect. We see it with heroin addicts as well. They use one dose of heroin, so to speak; and, after doing that every day for weeks, now they need to start using two to get the same high that they got with the first dose they were on, so to speak.

And the same can be said for pain management with opioids. When someone is on an opioid medication for a long period of time, their body gets used to it, and that's called opioid tolerance. It's not addiction. That's a different issue. It's just what the body does. It becomes tolerant,

such that now higher doses are necessary, which is why they have the different doses of the fentanyl patch, so that, if someone becomes tolerant with one dose but were getting pain relief up until the point where they got tolerant to it, you can go up to the next dose and now get some pain relief from that dose and wait for the tolerance to develop to the next dose. I hope that's a reasonable explanation.

Q Given that explanation and the context it provides, is opioid tolerance an important consideration for a clinician to consider before prescribing fentanyl patches to his or her patients?

A Absolutely. It's a critical piece of the information.

Q And why is that so important?

A Well, this particular product, the fentanyl patch, is only indicated -- and this is widely known among doctors. You don't give it to someone who's not had opioids before. It's only indicated for people who are already tolerant. And it's very detailed and -- for a doctor who may not know exactly how many milligrams of morphine, let's say, or oxycodone would make it safe to then give them a fentanyl patch at any dose.

So that's extremely important. The fentanyl patch should never be given to someone unless it's been established that they can safely tolerate -- since you're looking at

seventy-two hours constantly, even during the night when you're sleeping, we need to make sure that it's safe to give them this product and that they're tolerant to that dose that you're giving.

Q And we talked about the black box, and I want to draw your attention to a portion of it -- again, Exhibit J-12. Does the black box specifically refer to opioid tolerance?

A Yes.

Q And looking there at the point that -- the portion of the black box with the numeral 3 next to it, it reads: "Because serious or life-threatening hypoventilation could occur, Duragesic is contraindicated," and then what does the first bullet point say?

A "In patients who are not opioid tolerant."

Q We talked about the morphine that Mr. Guthrie had been prescribed on February 4 and then again on February 8th or 9th, depending upon which record you're looking at; and we talked about the seizure that he had on February 21st. Do you recall that?

A Yes.

Q Okay. How much morphine, again, was he taking between February 21st and March 4, when he received the fifty-microgram patch?

A Zero.

Q When Dr. Ball and his physician assistant prescribed

this fifty-microgram patch to Mr. Guthrie on March 4, was that prescription in accordance with the black-box warning that speaks to this issue of opioid tolerance?

A No, not at all.

Q Was that March 4 fifty-microgram-per-hour prescription consistent with the standard of care for a pain management physician?

A No.

Q Why not?

A Because, clearly, someone who's not been taking any opioids in the eleven days prior to writing the prescription would not be able to safely tolerate it. I guess we could be lucky and prescribe the certain dose. But the -- but the safe practice -- and our goal is to safely prescribe pain medications to people -- would not be consistent with giving any dose of a fentanyl patch.

Q And, if you look at the portion of the insert with the numeral "2," beginning with the word "Duragesic," do you see that?

A Yes.

Q Okay. Could you read that first sentence for us.

A Yes. "Duragesic should only be used in patients who are already receiving opioid therapy who have demonstrated opioid tolerance and who require a total daily dose at least equivalent to the twenty-five- microgram Duragesic patch."

Q And it goes on to give a definition or series of examples that apply to those patients who would be considered opioid tolerant to that twenty-five-microgram- per-hour dose. Right?
A Correct.
Q And what is that -- what are those examples or the definition that it provides?
A "Patients who are considered opioid tolerant" -- and, again, that's for the purpose of that starting dose of twenty-five micrograms -- are those who have been taking, for a week or longer, at least sixty milligrams of morphine daily or at least thirty milligrams of oral oxycodone daily or at least eight milligrams of oral hydromorphone daily or a equianalgesic dose of another opioid."
Q And, in going through Dr. Ball's records, we talked about all of these examples of opioid medications that had been prescribed to Mr. Guthrie, did we not?
A Yes.
Q And I've underlined -- we talked about the MS Contin, or the morphine. Right?
A Right.
Q Okay. Was there ever an instance, during the time that Mr. Guthrie was treated -- treating with Dr. Ball, where he ever consumed, at any point, anywhere close to sixty milligrams of morphine on a daily basis?

A No. No more than maybe one day.
Q All right. Same question with respect to the oral oxycodone. We talked about the Percocet. Right?
A Right.
Q What was our daily average that we established for that two-month period that he was on the Percocet?
A About three-and-a-half milligrams --
Q All right.
A -- per day.
Q And, in this case, we'd need about ten times that in order to make the patient tolerant to the twenty-five-microgram-per-hour patch.
A That's correct.
Q Is that fair to say?
A (Whereupon, witness moved head up and down.)
Q Okay. Hydromorphone. Again, that's the Dilaudid?
A That's right.
Q Any indication, during the time that Mr. Guthrie was taking Dilaudid for breakthrough pain, that he consumed, for a week or longer, at any point, that quantity of hydromorphone?
A No. Nowhere close.
Q Is it fair to say, Doctor, that, when Mr. Guthrie went to Dr. Ball's office for that March 4 visit to receive the fifty-microgram fentanyl patch, that he was completely opioid naive?

A Yes.
Q And the reason for that would be what?
A Because he -- he had not been taking any opioid for at least eleven days prior to getting that prescription.
Q Should fentanyl patches ever been prescribed by a pain management physician or any other doctor at any dose, twelve, twenty-five, fifty, seventy-five or a hundred, to patients who are completely opioid naive?
A No.
Q Is doing so at any dose a breach of the standard of care for a pain management physician?
A Yes.
Q I want to talk to you real quick about the lumbar blocks. We talked a little bit about that earlier. And these are the -- I guess they're termed lumbar sympathetic blocks that Dr. Ball administered to Donald Guthrie?
A That's right.
Q Okay. And I think we established that there were three different -- different sessions?
A Yes.
Q Okay. What was Donald Guthrie's response to those lumbar blocks?
A I think he said he thought they worked, at least temporarily.
Q How much fentanyl was used in those lumbar blocks?

A A total of a hundred and fifty milligrams -- a hundred and fifty micrograms.
Q Is a hundred and fifty micrograms of fentanyl that Mr. Guthrie received during those injections, is that, in any way -- given the means by which it was administered to the patient, is that in any way indicative of Mr. Guthrie's ability to tolerant fentanyl in transdermal form -- that is, by the patch?
A No, not at all.
Q And why not?
A It's like a totally different drug. It's being administered in a -- I would say intravenous. I think it was actually put within the mixture of that local anesthetic that was used through the needle. But it was not via the patch formulation, so it was going to get a pretty high dose of fentanyl for a short period of time in the bloodstream but be gone very, very quickly. It's metabolized -- or at least not in the bloodstream for very long, so it's really more of a short-acting form. It's like two different drugs. The fentanyl patch is a long-acting form of fentanyl. The fentanyl that is put through the needle, such as in the lumbar sympathetic blocks, would be very short-acting.
Q Let's move on and talk a little bit -- we talked about opioid tolerance. I want to talk a little bit about the distinction between acute and chronic pain. We've discussed

that a little bit already, haven't we?
A Right.
Q All right. Are there any ways, in your opinion, Doctor, in which you believe that Dr. Ball deviated from the standard of care in prescribing fentanyl patches to Donald Guthrie, based on the nature of his pain condition?
A Yes.
Q All right. And what are those?
A Well, that the pain condition was not a chronic pain, as in a pain that's not going to get better, that's gone on for six months or longer -- it was an acute pain, due to this meniscal-tear injury -- and that the fentanyl patch -- and, really, any long-acting opioid -- would not be appropriate, would be below the standard of care for the treatment of such type of pain.
Q All right. And, again, referring back to the black-box warning, we see that there's a contraindication in those who are not opioid tolerant. We covered that already. And then, underneath that, that refers to the use of the fentanyl patches in the management of acute pain that we've been discussing. Right?
A That's right.
Q Okay. Why should a physician -- why is it a breach of the standard of care for a physician to prescribe fentanyl patches to somebody who is suffering from an acute-pain

condition?
A Well, as I mentioned before about the constant nature of that fentanyl patch -- in other words, it's like an infusion of the drug twenty-four hours a day at roughly the same level, certainly not a level you can control, so that, if your pain hurts more right now, you can't make that patch give you more of the opioid or the fentanyl. So the pain that's acute pain is very commonly known to be labile in nature. What I mean by that is it changes throughout the day -- a lot of times, with certain activities, getting up and down. If somebody's laying and resting, they may not have any pain. Acute pain, that is pain from an injury or some trauma, like pain from a meniscal tear, is going to change throughout the day. So the fentanyl would be the worst option, as far as effectively matching the pain that someone has, that's going up and down, with the constant level of narcotic opioid in the blood. So that's why fentanyl would be inappropriate for acute pain.
Q All right. And then, again, we established, based on that initial presentation with Dr. Ball on December 7th, that he had complained, after suffering this knee injury, and described his pain as intermittent. Do you recall that?
A That's right.
Q And, again, the insert states that fentanyl is contraindicated for this condition? Yes or no?

A Yes.
Q I want to talk a little bit about something that we've heard -- a pain condition that we've heard about during this case called RSD, or reflex sympathetic dystrophy. We talked about it a little already. Is that the same thing as complex regional pain syndrome?
A Yes. Type I specifically.
Q Okay. Have you done any research, any clinical research, in the field of RSD- or CRPS-type work?
A Yes.
Q What can you tell us about that?
A I was one of the primary investigators of a multicenter trial. It was an investigational new drug that a company called Celgene was trying to get approved, specifically for RSD, also called CRPS Type I.

I conducted the study over a period of about two years while I was at Fort Bragg, Womack Army Medical Center. We got it approved through our hospital ethics committee. And we enrolled patients. We had to enroll them according to some pretty strict protocol to make sure they had RSD and not just some other variety of pain.
And then the drug, called -- "lenalidomide" is the generic name for it -- was used compared to a placebo, a sugar pill, to see if that would help these patients over a long period of time.

Q What causes RSD or CRPS Type I?
A Nobody knows exactly what mechanism in the body or nervous system that causes it from sort of the body's perspective. It's widely known that it starts with some sort of an injury, commonly minor surgical operations -- carpal tunnel, for example.

Every now and then, someone, even though you expect their pain to go away after surgery, their pain gets worse right after surgery. Sometimes, it's something as simple as like an ankle sprain; and then the whole foot just gets painful, way more than you would expect from just an ankle sprain. So it typically starts with some sort of an event of an injury or surgery.

Q Is there a proper means by which a clinician must diagnose RSD?
A Yes.
Q Okay. And we -- we talked earlier very briefly about the RSD symptoms that were noted during Mr. Guthrie's initial December 7 visit -- and I may have butchered the terminology somewhat -- but cutaneous allodynia one of the -- was one of the symptoms that's documented here during this December 7 visit. Right?
A Yes.
Q And we talked about what that was.
A Yes.

Q And then there's the reference to: "No hyperhidrosis." And "hyperhidrosis," I think you described earlier, is a fancy term for sweating. Right?
A That's right.
Q Do you have an opinion, based upon looking at this, Doctor, as to the accuracy of the diagnosis of RSD in Mr. Guthrie's case?
A Yes.
Q And what is that?
A It's that he did not qualify, even closely qualify, for the diagnosis of reflex sympathetic dystrophy.
Q And why is that?
A Well, it's widely known, among pain specialists, of a set of criteria; and they give some wiggle room within the criteria. There are four general types of symptoms and signs that we look for, and every pain doctor is aware of these. The type of pain is one of them. It's this allodynia type of pain I was mentioning earlier. That's one of them, the type of pain.

The second one is called vasomotor symptoms, which would be temperature changes or color changes to the skin, particularly compared to the other extremity, as your normal extremity.

The third category is motor problems, such as muscle wasting or poor range of motion, can't move their extremity

very well; has weakness, motor weakness.

And then the fourth category is called pseudomotor, and that just means the sweating-type symptoms, is there a difference between the two extremities in the way that they sweat or swell, called edema, the swelling.

And, in this case, the -- and, when we do a clinical trial, we look for all four of them. We want all four of those. And the most liberal of recommendations, through textbooks and authoritative medical journals, would say you should get at least three of those, the patient complaining of at least three of those four general areas that are very common for this reflex sympathetic dystrophy, instead of just one. In this case, there was just the one aspect that would be consistent with an RDS diagnosis, not any more than the one out of the four.

Q And, based on that and your review of this chart, can you say, in medical probability, whether or not Donald Guthrie actually suffered from RSD?

A Yes. He did not suffer from RSD.

Q And is RSD considered to be a chronic or acute condition, or can it be either/or?

A Well, I suppose the first part -- when someone first gets an injury, in the first few months after getting that injury and it's getting worse -- such as after, again, like a minor surgery, operation of some sort -- that be would

considered acute, because it's still early on. But it very commonly turns into a -- the majority of them turn into a chronic pain that may last years. Not a lifetime, but can last years for sure.

Q Is there any question that Donald Guthrie suffered from an acute pain condition at the time he was prescribed the fentanyl patch?

MR. BROCK: Objection to form, argumentative.

THE COURT: You want to rephrase? Argumentative or --

MR. BROCK: Yes.

MR. PATE: I don't see how it's argumentative.

BY MR. PATE:

Q Doctor, what is your opinion as to whether or not Donald Guthrie was suffering from an acute or chronic pain condition at the time that he received a prescription for the fentanyl patch on March 4 and March 18?

A He was suffering from acute pain due to a meniscal tear in his knee.

Q Was Donald Guthrie suffering from a chronic pain condition, in the form of RSD, at any time during his care and treatment with Dr. Ball, to a reasonable medical probability?

A No.

Q Now, wasn't there a nerve conduction study that was done --

A Yes.
Q -- on Donald Guthrie? Didn't that show that he had RSD?
A No. In fact, even in that research study I told you about, we -- we didn't do nerve conduction studies either. The diagnosis is made based on those clinical criteria, asking the patient what they feel and looking for those same signs of those four categories and making sure there's not a potential other something going on, such as a meniscal tear or other injury, that could explain the pain.
Q What about the effectiveness of those lumbar sympathetic blocks that were done in those three instances by Dr. Ball? Don't those show that Donald Guthrie had RSD?
A Well, again, they're not used to initially diagnose it. I think they're helpful. If I can inject a local anesthetic and get a temperature change -- and that's the standard of care for doing a lumbar sympathetic block, is to measure the temperature before the injection of this anesthetic into these special nerves that affect temperature as well and then get the temperature afterwards and make sure it's at least one degree Celsius higher after the procedure. In this case, the way the procedure was performed is a little gray because the temperature wasn't measured. And, of course, that hundred and fifty micrograms and fentanyl that was injected, that, in itself, can take someone's pain

completely away.
Q All right. Well, let's say, for the sake of argument, Doctor, that we are dealing with an RDS patient in Donald Guthrie. Is there any indication that he treated with opioid medications prior to his knee injury?
A No. There's nowhere in the pharmacy records, that I could see, that indicated any opioid therapy.
Q And presuming, again for the sake of argument, RSD in this patient, are opioids, like fentanyl, are they appropriate to treat that condition?
A No. This condition is widely known to get worse in some cases -- there's a phenomenon called opioid induced hyperalgesia. That mean opioids can cause worsening pain, in a paradoxical way, particularly with nerve-related pain. And, in RSD, that would be one of the last medication categories I would ever choose. It could still be on the list of possibilities, but very much at the bottom.
Q Are there other things that could have been done, for example, to treat an RDS condition -- again, presuming, for the sake of argument, that we actually have one in this case -- that don't carry with them a risk of respiratory depression like fentanyl would?
A Sure.
Q What are those?
A A huge number of categories of drugs. There are

some that are specific to nerves, such as different types of antiepileptic drugs, even different antiepileptic drugs that were different from the ones Mr. Guthrie was already taking for his seizure disorder. Those are commonly used, particularly in higher doses, and are known to be very effective.

Also, a category of drugs called tricyclic antidepressants and serotonin-norepinephrine-type antidepressants are also known to be relatively effective and to increase the dose as they tolerate the side effects. They don't have respiratory depression associated with them. But they are way higher on the list of likely to improve someone's RSD pain, if they do have RSD, than opioids would be.

Q Thank you, Doctor. I want to ask you a little bit, moving on, about whether Donald Guthrie had any respiratory comorbidities that counseled against the use of fentanyl patches in this case.

A He did have respiratory comorbidities, yes.

Q I show you a portion of the FDA labeling. This will be Page 3, left-hand column, the portion of the insert that corresponds to the numeral 4. Could you read the first sentence of that portion of the highlighted insert corresponding to Number 4, Doctor.

A "Duragesic should be used with extreme caution in patients with significant chronic obstructive pulmonary

disease or cor pulmonale and in patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia or preexisting respiratory depression."

Q Would it be fair to characterize, Doctor, Donald Guthrie as somebody who was predisposed to respiratory depression?

A Yes. That was actually demonstrated in a sleep study that I had reviewed as a part of his records.

Q I'll get to that in a minute. Putting aside the sleep study, what are some of the other comorbidities that were documented in Dr. Ball's records that you believe predisposed him to respiratory depression?

A Morbid obesity -- that's a big one -- as well as his history of known COPD, chronic obstructive pulmonary disease.

Q And do you recall what Donald Guthrie's weight was when he initially presented to Dr. Ball on December 7?

A Three hundred eighteen pounds.

Q Looking at Page 38 of Dr. Ball's records, approximately three-and-a-half months later, March 18, had his weight increased or decreased?

A It had increased.

Q To what?

A To three hundred and thirty-six pounds.

Q So, over the course of this approximately three-and-a-half-month period between December 7 and March 18

of the following year, he had increased in weight from three-eighteen to three-thirty six?
A That's right.
Q Okay. Did his Body Mass increase?
A Yes, to right about forty.
Q And what was his Body Mass Index during his initial visit?
A About thirty-eight.
Q So he'd actually gained weight?
A Yes.
Q Did his gaining of weight during this time period, did that increase or decrease his predisposition to respiratory depression, particularly during periods of sleep?
A It would have increased it.
Q Going back to the black box, Doctor, following up on the sentence that you just read corresponding to Numeral Number 4, subsequent to this portion that discusses using Duragesic in patients with chronic obstructive pulmonary disease and so forth, what does this portion of the insert go on to say about the course of treatment in terms of analgesics that that patient should undertake?
A It just simply describes that, even usual -- normally therapeutic doses, normal doses, would increase respiratory -- would decrease respiratory drive to the point of apnea; and, in these patients, nonopioid analgesic

alternatives should be considered, and opioids should be employed only under careful medical supervision at the lowest effective dose.

Q Now, you mentioned the sleep study earlier. This is exhibit J-9. Is this the sleep study, Doctor, that you reviewed, the one that took place in 2007?

A Yes.

Q Okay. And this was done at the Hamilton Medical Sleep Disorder Center? Do you see that, Doctor?

A Yes.

Q The study itself, the respiratory -- respiratory events are documented. What does -- what do these respiratory events document in terms of the -- I'm not sure I'm going to pronounce this correctly, hypo -- hypopneic events?

A Hypopneic events.

Q Thank you. What does this study report in terms of that?

A Well, it reports that there were no episodes where Mr. Guthrie stopped breathing completely; but there were numerous episodes where the air movement, as he was breathing during sleep, was so deficient that it dropped his oxygen level in his bloodstream on these eleven on so occasions, it says here.

Q Okay. And how low did it drop, his oxygen level, during sleep?

A I think the lowest was eighty-six percent.
Q And what do you mean -- do you consider normal?
A Normal would be, at the very least, ninety-three or ninety-four percent. Normal is usually higher than that, but the range is ninety-three to one hundred.
Q And there's also some recommendations on the following page, a portion of which I've highlighted, that were made subsequent to that sleep study, specifically Number 3. What does that say?
A "Avoidance of alcohol and sedative medications."
Q And why is it important for a patient that's demonstrated the results that he did in this particular sleep study -- why would it be important for that patient to avoid alcohol and sedative medications?
A Well, because it's widely known that alcohol and sedative medications further decrease or inhibit your respiratory drive. So, if you're already, such as Mr. Guthrie, having episodes during normal sleep, without taking any sedative medications, having these episodes of decreased oxygen and decreased airflow, then that would only get worse if you add a respiratory-depressant-type drug like an opioid.
Q Now, there were a number of -- when Mr. Guthrie went in for his visits with Dr. Ball, they did vital signs; and you looked at some of those vital signs. Right?
A That's correct.

Q Okay. And, in terms of the 02 sats that were demonstrated, those were all in the -- pretty much in that range that you talked about, ninety-two, ninety-three, ninety-four? Is that right?
A That's right.
Q What significance does that have to you in the context of prescribing fentanyl to a patient who is predisposed to respiratory depression?
A Well, I think the importance to me, after seeing them already on opioid medications -- ideally, someone who's continuously been on an opioid -- is so that I know that this normal number is normal with the opioid working. In Mr. Guthrie's case, almost all of these, if not every one of these visits to the office where he had a normal oxygen level, he hadn't been on much, if any, opioid at all.
Q And, of course, when he went to Dr. Ball's office, did he -- was he wheeled in asleep on a gurney; or did he walk in upright, alert and awake?
A Right. He was -- he was obviously awake. And it's also widely known that opioid overdoses, as far as to stop you from breathing, don't happen wide awake. There's no such thing as somebody just being wide awake and they fall over dead from opioid toxicity. The respiratory depression occurs in conjunction with sleep. You may fall asleep at first, from being very sleepy or tired or sedated from the side effects of

the medication; and then, after you're asleep, you now start having the decreased respirations. So, when he came to Dr. Ball's office, he was obviously awake; and that's why he had a normal oxygen level at that point.

Q Going again back to the portion of the package insert that discusses prescribing fentanyl patches to persons with chronic pulmonary disease, could you read the first sentence of that portion captioned: "Chronic Pulmonary Disease," Doctor.

A Yes. "Because potent opioids can cause serious or life-threatening hypoventilation, Duragesic should be administered with caution to patients with preexisting medical conditions predisposing them to hypoventilation."

Q Do you, in your opinion, believe that Dr. Ball and his staff prescribed fentanyl, either at the fifty-microgram dose or at the seventy-five-microgram dose, with the exercise of caution?

A No.

Q Was prescribing fentanyl patches at any dose to someone with Donald Guthrie's comorbidities -- the COPD, the hypopneic events that were demonstrated in the sleep study -- is that consistent with the standard of care that's applicable to Dr. Ball?

A No.

THE COURT: Why don't we let the jury stretch for

just a minute while you look through your notes. I don't think we need another break right now, but maybe we could stand and stretch just for a second.

Mr. Pate?

MR. PATE: Yes, Your Honor.

THE COURT: The witness would like a comfort break.

MR. PATE: I certainly have no objection to that.

THE COURT: Mr. Brock?

MR. BROCK: Oh, absolutely not.

THE COURT: All right. It turns out we're going to take an afternoon break, so the jury can be excused first.

(Whereupon, the jury left the courtroom at the 2:51 p.m.)

THE COURT: I don't have a courtroom deputy right now, so we're in recess.

(Whereupon, a recess was taken from 2:51 p.m. to 3:03 p.m.)

THE COURT: Sorry for the abrupt break, but I thought it was necessary. And I guess, just for the record, it was getting warm in here.

(Directed to the Witness) If you'll sit down, we will get the jury; or you can stand, if you want to, till the jury comes in.

(Whereupon, the Jury returned to the courtroom.)

THE COURT: Have a seat, and I'll remind you you're

still under oath.

Mr. Pate?

MR. PATE: Yes, Your Honor.

THE COURT: Oh. Please wait until we get our jury seated. I'm sorry. Okay.

BY MR. PATE:

Q Dr. Grubb, are you ready to proceed?

A Yes.

Q Okay. I'm going to try to push this along. Another topic I want to cover with you real quick -- well, before I do, I want to step back real fast. We talked about prescribing fentanyl for patients that are opioid intolerant. Right?

A Right.

Q We talked about Donald Guthrie's comorbidities. Right?

A Yes.

Q And we would talked about acute pain versus the chronic pain as well. Right?

A That's right.

Q In your opinion, is prescribing fentanyl for an acute pain condition of the kind that Donald Guthrie had in transdermal form a breach of the standard of care applicable to pain management physicians?

A Yes.

Q Let's talk about going from the fifty- to the seventy-five-microgram patch on March 15. Are you with me?
A Yes.
Q "Dose titration." What does that term mean, to titrate a dose of a medication?
A It means to increase it or decrease it so as to get a better effect or minimize side effects.
Q I've heard, at times, a physician say: "I'm going to titrate to clinical effect." What does that mean?
A That just means I want to start at a low dose, in case of side effects or some other reason, and gradually increase the dose until I reach the effect that I want.
Q And, part of that effect, does that include not any sort of signs of toxicity or adverse side effects?
A That's right. The same could be said for blood pressure. You wouldn't want to give too high of a dose and their blood pressure be so low that they pass out and that kind of thing.
Q And we established, on March 18, that, when Donald Guthrie returned to Dr. Ball's office, his dose was increased from the fifty-microgram patch to the seventy-five-microgram patch.
A That's right.
Q And this was two weeks -- again, for context and background -- after he'd been given those five fifty-microgram

fentanyl patches to be replaced every three days.
A That's right.
Q I'm going to go to Page 38 of Dr. Ball's records. We've looked at this already. But it shows that Donald -- again, when he returned to Dr. Ball's office, he had how many of those fentanyl patches remaining?
A Two remaining.
Q Okay. And, if he had been taking the patches prescribed to him on March 4th, the fifty-microgram patches, and replacing them once every three days consistently, he should have had how many unused patches remaining?
A Zero.
Q According to this, it says he has how many left?
A He had two.
Q All right. In light of that fact, Doctor, is it accurate to say that Donald Guthrie was tolerating the fifty-microgram fentanyl patch during that two week period without any complications?
A There's no way to tell, because all five -- he clearly wasn't taking it consistently with consecutive patch applications.
Q Do we even know whether Donald Guthrie was actually wearing a patch during this March 4th visit, a fifty-microgram patch?
A No, we don't.

Q Can you adequately gauge -- as a clinician, can you adequately gauge whether a patient is adequately tolerating a given dose of fentanyl patch if they aren't even applying or replacing those patches on a regular basis every forty-eight or seventy-two hours consistently?
A There's no way to know.
Q Did Dr. Ball and his physician assistant act within the standard of care in increasing Mr. Guthrie's fentanyl-patch dose from fifty to seventy-five micrograms per hour on March 18?
A No.
Q Why not?
A Because there hadn't been an established pattern of consistent use of the fifty-microgram patch.
Q Okay. Any other reasons?
A Well, the biggest one that I see -- I shouldn't say biggest. I guess it's just as bad as not knowing how many of those fourteen days he actually wore the patch. But, when this particular product, unlike other long-acting opioids, is titrated -- in other words, when the dose is increased -- it, for safety reasons, also needs to be based on the use of additional -- we talked about breakthrough pain -- additional short-acting opioids that one would be taking in addition to that fifty-microgram patch. It's very important to count those milligrams, too, and increase the dose of the fentanyl

patch in a very strict fashion of how much they've been taking of their additional, in this case, Dilaudid. He was taking Dilaudid in addition to the fentanyl patch. And that Dilaudid he didn't take very much of, so that wouldn't justify increasing to the next level up of the patch.

Q I'm going to point you to a portion of the package insert again. It's the last page, right-hand column, the highlighted portion, the last paragraph of the section captioned: "Dose Titration." Is this the portion of the answer that you were referring to, Doctor, in terms of the supplementary -- supplementary Dilaudid that Mr. Guthrie was taking?

A Yes, that's right.

Q And could you read that for the jury, please.

A Yes. It says: "Appropriate dosage increments should be based on the daily dose of supplementary opioids using the ratio of forty-five milligrams per day, per twenty-four hours, of oral morphine to the twelve-point-five microgram patch size in Duragesic dose."

Q And, based on what we know about Mr. Guthrie's pill counts with respect to the Dilaudid, was he consuming -- or do we know that he was consuming twelve-point-five equivalent of forty-five milligrams every twenty-four hours of oral morphine?

A No. He definitely wasn't consuming even near that

amount.
Q And what's that based on?
A On his use of the Dilaudid. The pill count that was done reflected that he had only taken eighteen of the two-milligram Dilaudid tablets over that two-week period, which isn't anywhere near even the forty-five milligrams to bump it up another twelve-point-five increment on the patch.
Q Okay. And I'll draw your attention over here to another section. Again, this is the same last page of the package insert. These are the dose conversion guidelines contained in what's captioned: "Table C." Do you see that?
A Yes.
Q All right. And we talked about the fifty-microgram patch that Mr. Guthrie was prescribed on March 4. What does this indicate is -- there's a range that's given here in terms of daily analgesic usage on a milligram-per-day basis. Right?
A Yes.
Q And we've got various -- various opioids here of -- of various potencies. Right?
A That's right.
Q And then there are these corresponding ranges; and, depending upon what the range is, it corresponds to a given patch -- recommended patch dose. Right?
A That's right.
Q So what is the minimum, the bottom end of the range,

of the daily oral morphine intake that Mr. Guthrie would have had to have had in order to be eligible to safely use the fifty-microgram-per-hour patch?

A A hundred and thirty-five milligrams of morphine daily.

Q And how much oral morphine was Mr. Guthrie taking on a daily basis at the time he was prescribed this fifty-microgram patch?

A None.

Q With respect to the seventy-five-microgram-per- hour dose, when it was increased on March 18, what is the minimum dose of oral morphine, according to this chart, that Mr. Guthrie would have had to have been taking to safely use the patch at that dosage?

A No.

Q Well, what is -- what is the minimum dose?

A Well, the minimum dose of the oral morphine to go up to the seventy-five-microgram patch would be two hundred and twenty-five; and, in this case, he had -- even if he had been using continuously the fifty-microgram patch, in order to qualify for a dose increase -- safely, at least -- he would have had to take that additional amount of Dilaudid in a range much higher than the average of two milligrams or so he took per day.

Q And, of course, as you mentioned previously, was Mr.

Guthrie actually taking the fifty-microgram patch consistently and replacing it consistently during that two-week period.

A No.

Q Was it a breach of the standard of care for Dr. Ball and his physician assistant to increase Mr. Guthrie's dose of fentanyl patch from fifty micrograms per hour to seventy-five micrograms per hour on March 18, 2010?

A Yes.

Q Given your understanding of Mr. Guthrie's pain condition as you've described it, are there alternative treatment modalities, alternative therapies, that you believe, given his clinical presentation, that would have been more appropriate during this time period, this three-and-a-half-month time period, he was treating with Dr. Ball?

A Yes. The standard management of a meniscal tear, which would be Tylenol, maybe some short-acting opioid medications until such time as you have surgery to correct the meniscal tear, ice therapy, physical therapy. That's about all I can think of.

Q Mr. Guthrie, of course, had surgery on his knee. What was the date of that?

A March 23rd.

Q All right. Do you believe it would have been prudent for a clinician, a pain management clinician, to have

waited to see the outcome of the surgical result --
A Most --
Q -- before undertaking opioid therapy?
A Most definitely.
Q We spent a lot of time, Doctor, talking about the guidelines and the warnings and so forth that are set forth in the black box and the remainder of the full prescribing information. Do you have an understanding -- I understand you have testified in previous cases about the sufficiencies -- sufficiency of the warnings in various incarnations of this FDA insert over the past several years. Is that right?
A Yes, I have.
Q And, through that experience, have you gleaned an understanding as to how these warnings actually come about and what they're based upon?
A Yes.
Q Okay. Why does the FDA include these warnings and contraindications that we've been discussing in the package insert and put certain warnings inside of a black box?
A Well, it's because they get information and data of events, adverse events, that happen. The drug companies are required to present all of the adverse-event information that they get as a company; and, in products such as this one, where there are events of death, accidental death, they -- that information goes into warning the doctors through this

special black-box warning mechanism.

Q And so these reports of adverse events and death, they can actually have an impact on the patient labeling?

A Absolutely.

Q Are you familiar the MedWatch system?

A Yes.

Q Okay. What can you tell me about that? What function does that serve in sort of creating the different types of warnings and where they go in the package insert?

A Well, the MedWatch system is another mechanism with the FDA whereby they get alerts of events that happen -- deaths being the worst one, but other events as well that would be associated with a particular drug -- and then the FDA can convey that message to the prescriber. They usually do in the form of what we call a dear-doctor letter, where the FDA gives a summary of some MedWatch reports, so that the doctors can be more aware. Even beyond just telling them to read the black-box warnings, special warnings are --

MR. BROCK: Excuse me, Your Honor. This is outside the disclosures.

THE COURT: Mr. Pate?

MR. PATE: It's not opinion testimony, Your Honor. He's just basically giving the factual basis for which the warnings in the package insert are created. I don't think he's offering any opinions at this point.

MR. BROCK: Brief response?
THE COURT: Yes.
MR. BROCK: He started out talking about his expertise and his position; and so, yes, he is giving an opinion.
THE COURT: I'll sustain the objection.
BY MR. PATE:
Q Okay, Doctor. Let's move on. One of the things that you did mention were the dear-doctor letters. I've also heard them referred to as "public health advisories"? Is that another term that's sometimes used?
A That's right.
Q What can you tell me -- what understanding do you have about any public health advisories or dear-doctor letters that have been issued to physicians with respect to the prescription of fentanyl patches?
A Well, there have been numerous of these letters to physicians over the years with the fentanyl patch, particularly noting that there are reports also of, in the past, doctors not paying close enough attention to the recommendations of the black-box warning. There have been at least two that I've seen.
Q And do you recall the dates of those?
A One was in '05, and then there was a followup to that letter in '07, reemphasizing that, apparently, there are

still some cases out there of people -- of doctors not prescribing this in strict conformity with the labeling.

Q Okay. And I want to show you one such health advisory, Doctor, preadmitted as Exhibit J-24. And there's a portion that I have highlighted. Could you read that to the jury, please.

A Yes. "Despite issuing an advisory in July 2005 that emphasized the safe use of the fentanyl patch, FDA continues to receive reports of death and life-threatening side effects in patients who use the fentanyl patch. The reports indicate that doctors have inappropriately prescribed the fentanyl patch to patients for acute pain following surgery, for headaches, occasional or mild pain and other indications for which a fentanyl patch should not be prescribed."

Q I want to show you another public health advisory, Doctor. This has been preadmitted as Exhibit J-22. Again, there is another highlighted portion I would like you to read to the jury.

A "Deaths and overdoses have occurred in patients using both the brand name product, Duragesic, and the generic product. The directions for using the fentanyl patch must be followed exactly to prevent death or other serious side effects from overdosing with fentanyl. These directions are providing in the product label and patient package insert."

Q And the product label and the patient package

insert, is that what we've been discussing today?
A Yes.
Q There's another section -- again, this is in the public health advisory marked as Exhibit J-22 -- that I've highlighted. Could you read that to the jury.
A "Patients who are using the fentanyl skin patch and their caregivers should be told about the directions for safe use of the patch and should follow the directions exactly. These directions are provided in the patient package insert."
Q Did Dr. Ball or his office staff prescribe either the fifty-microgram fentanyl patches or the seventy-five-microgram patches in any fashion which would be considered following the directions in the package insert exactly?
A No.
Q One of the things that we've heard about this case, Doctor, and I'm sure Mr. Brock will speak with you about, is something called a doctor's clinical judgment. Are you familiar with that concept?
A Yes.
Q Medical judgment?
A Yes.
Q We've heard that medicine is not a cookbook. That is, you don't open up the book and you follow the directions exactly. It's as much art as it is science. As a clinician,

I take it that you are intimately familiar with the concept of clinical discretion or clinical judgment. Is that fair to say?

A Yes, it is.

Q And, in general terms, can you explain that concept, clinical judgment, medical discretion, when it comes to caregiving of patients?

A Well, the practice of medicine involves taking a lot of information in from patients and using your best judgment to do what you feel like is best for the patient, and then balancing that is always our principal priority of what we call first do no harm, which is, whatever we do, we at least need to do it in a safe manner. Even if we're not effective as being doctors and helping people, we certainly don't want to hurt them. So the medical judgment goes into making decisions, whether or not it's exactly written in a textbook a certain way or in a journal article a certain way. That's where the doctor's experience and judgment comes into play.

Q Okay. Exercising that experience and judgment, you yourself have occasionally prescribed medications off-label, I guess is the term, using your own clinical discretion and judgment. Right?

A Yes. In a -- in a sense, yes.

Q Okay. And, when you -- when you say "in a sense, yes," what do you mean? What do you mean by that?

A Well, I would -- I don't ever see a black-box warning as something that I'm going to go off-label with, meaning ignore a black-box warning and just do what I want to do. Off-label -- most physicians think of off-label as meaning giving a certain medication maybe for a diagnosis or something that hasn't been studied. There are a lot of medications out there that we use for other types of conditions that maybe, originally, weren't studied for those conditions; and so the FDA wasn't able to put in certain guidelines, and so we could consider that off-label. There are times when, if it doesn't seem to affect the safety of a certain treatment, I would use a different drug than what even a textbook might recommend or even something in a different setting than what a package insert, in some ways, would recommend. But not in a black-box warning. That's a totally different type of label in my opinion.

Q Okay. And, in your opinion, does a physician prescribing fentanyl patches have the clinical discretion to deviate from the black-box warnings in prescribing fentanyl patches and still act within the standard of care applicable to that practitioner?

A No.

Q Why not?

A Because this is what has been found across the whole country, informed to us through these letters from the FDA,

that can cause death; and since, again, I don't want to harm anyone, I have to look at this -- it would be the same when it comes to other medications that might be dangerous. Most medications aren't super dangerous and don't have a black-box warning; so, when I see the big black box, I have to pay attention to that and understand that the standard of care would be a practice in accordance with the black-box warning due to the risk of death and injury.

Q In addition to the black-box warnings, we've talked about some of the public health advisories and dear-doctor letters that substantiate that. Right?

A That's right.

Q Does the package insert itself also contain a separate statement about the obligation of healthcare practitioners to prescribed the patches, fentanyl patches, in strict conformity with the directions?

A Yes.

Q And I'm going to show you a portion of that. Can you read -- again, this is the fifth page, right-hand column, of Exhibit J-12, the fentanyl package insert. The highlighted portion -- as soon as it goes into focus. The highlighted portion of the insert, what does that read, Doctor?

A "With all opioids, the safety of patients using the products is dependent on their healthcare practitioners prescribing them in strict conformity with their approved

labeling with respect to patient selection, dosing and proper conditions for use."

Q And did Dr. Ball and his staff prescribe fentanyl patches to Donald Guthrie in strict conformity with the approved labeling with respect to Donald Guthrie's selection, dosing and proper conditions for use?

A No.

Q Was the failure to do so a violation of the standard of care applicable to Dr. Ball in your opinion?

A Yes.

Q Now, we know that Don received -- Donald Guthrie received that final prescription for the seventy-five-microgram patch on March 18. We covered that. Right?

A Yes.

Q And I think, as you mentioned, he had the arthroscopic surgery to his knee that was done on March 23.

A That's right.

Q And, according to what you've reviewed, when, after that surgery, was he found unresponsive by his wife?

A The following morning, on the 24th.

Q Okay. In your opinion, Doctor, is there a correlation between the timing of the surgery that Mr. Guthrie had to his knee on the 23rd and the timing of his becoming unresponsive and subsequent death?

A Yes.

Q Okay. And can you explain that to the jury.
A Well --
MR. BROCK: I don't -- that's not in the disclosure, Your Honor.
MR. PATE: We already had a limine on this, Your Honor. He's allowed to provided opinions about cause of death. That's exactly what this testimony is intended to elicit.
THE COURT: And, Mr. Brock, do you want to tell me how it is not covered by the motion in limine earlier?
MR. BROCK: I'm not objecting that he can give an opinion as to the cause of death as being related to the fentanyl patch, and that was ruled on. But this is a new aspect, that they didn't talk about the timing, which was not disclosed in disclosures.
THE COURT: And, if that's the case --
MR. PATE: It goes directly to the cause of death from the fentanyl patch. This is part of his analysis of the big picture.
THE COURT: Was it disclosed in the report or the disclosures?
MR. PATE: Well, the report discloses that he believes the prescription of the fentanyl patch to Donald Guthrie was the proximate cause --
THE COURT: Well, here's what I'm saying, Mr. Pate.
MR. PATE: -- of his death.

THE COURT: Keep your questions to what is disclosed in the report. And you'll have to rephrase at this point.
BY MR. PATE:
Q Let me ask it this way, Doctor. Donald Guthrie died -- or became unresponsive in around the twenty-four-hour time period between -- subsequent to the surgery. Right?
A That's right.
Q Why is that?
A Well, in my opinion, it's because the surgery worked and took away the pain stimulus that the fentanyl patch was treating, so -- it's widely known, when you take away the pain, when someone's on a narcotic opioid medication treating the pain, now you have more toxicity associated with that opioid medication. In other words, the risk of respiratory depression goes up when you take the pain away.
And since he had the surgery on the 23rd which corrected, repaired, his meniscal tear, he, in my opinion, got better with the pain as well and then was still getting this constant level of high-dose fentanyl in his bloodstream for the following twenty-four or so hours and that that's what caused his death.
Q And just elaborate a little, if you would, on how it is that a pain condition could actually have a counteractive effect on the respiratory-depressant effects of narcotic analgesics like fentanyl.

A Well, it's widely known as well that pain increases your breathing. The opioid medications have the opposite effect on that, and so the -- the breathing can even be used as an indicator of how well one is being treated with a particular opioid. We even do that in the operating room setting by monitoring the respiratory rate and dosing the opioid medications accordingly. When the pain is gone -- and we see it, again, in operating-room settings. It's been widely published that, when the pain is gone -- such as, let's say, a nerve block is given to someone after a surgery that then takes their pain away. If you've just given them a big dose of narcotic, you have to watch them really closely, because they're a lot more likely to stop breathing because they don't have this antagonistic effect of the pain. That's just something that's known among anesthesiologists in particular.

Q Have you, as part of your review of this case, looked at the autopsy mortgage of Dr. Metcalfe?

A Yes.

Q And what was the final cause of death determination that was made by Mr. Metcalfe?

A Fentanyl intoxication.

Q Did you also read the deposition of Donald Guthrie's wife, Karen Guthrie?

A Yes.

Q Is there anything described in her deposition about the circumstances of Mr. Guthrie's death that is consistent with what is typically seen in deaths from opioid induced respiratory depression?

A Yes.

Q What are those?

MR. BROCK: Again, not disclosed, Your Honor.

MR. PATE: This was specifically addressed in the motion in limine, that he would be providing testimony about the circumstances of death that were observed prior to his becoming unresponsive and how those factored into his cause-of-death determination, which I believe the Court said he was free to offer in this case.

THE COURT: Well, if you'll both look at Document 236, Page 4876, you'll see exactly what I said about that.

MR. PATE: Okay. I don't have it in front of me, but...

THE COURT: Mr. Brock?

MR. BROCK: I've made my objection.

THE COURT: I guess I'm not understanding the full extent of the parties' argument, so I'm going to ask the jury to take a quick break.

(Whereupon, the jury left the courtroom at 3:31 p.m., and the following took place outside the hearing of the jury.)

THE COURT: Here's what the Court recalls, that the Defendant was challenging whether Dr. Grubb was qualified to offer an opinion regarding Mr. Guthrie's cause of death because -- essentially, the argument was that Dr. Grubb had admitted that he wasn't qualified to do so. At least that was the motion. I believe he was saying that, from a medical-pathology standpoint, he would defer to a cardiologist or -- I mean, I can't read it word for word. But the Court ruled that, based on his own experience as an anesthesiologist and pain management -- pain management physician, who's familiar with the risks, and based on Dr. Grubb's deposition testimony that he'd seen patients in his own practice that had taken too much of an opiate, he stated that the mechanism of death was very similar to those that he had seen in his own practice.

And the Court ruled that, based on those arguments, that Dr. Grubb was qualified, based on his own experience, and that his inability to consider certain other aspects would go to the weight of his opinion. The Court feels like a different argument is being made here, which is that -- that the basis for his opinion wasn't disclosed. At least that's what I'm understanding you to argue, Mr. Brock. And I wanted to hear from you if -- I mean, in a sense -- as I've said repeatedly now, I don't have his report. I don't know what he disclosed. So I don't know if he disclosed, as part of the

basis for his opinion, that he had read Ms. Guthrie's deposition or if it had even been taken at the time or if he had talked to her. I'm at a loss at this point to address what I perceive as being a current argument, that is -- is leaving me without full information.

So, Mr. Brock, I'm going to get you to expand on it if you want to. I mean, I think the lawyers ought to be able to agree whether or not something's disclosed in a report or in a deposition without me having to read the entire deposition and the entire report, which I can't do in the middle of a trial. You should be able to point out where it was disclosed, if that was the basis for his opinion, or if this is some sudden surprise, because I'm understanding you, Mr. Brock, to be objecting to him saying that one of the things he considered in coming to the conclusion that Mr. Guthrie's cause of death was consistent with what he had seen in his experience was when he started talking about Ms. Guthrie's deposition.

MR. BROCK: Well, yes, Your Honor.

THE COURT: And I think that probably part of -- without knowing, but just guessing, based on the numerous motions in limine, I assume that he's going to talk about the fact that there was heavy breathing and snoring, you know, and then there wasn't. And...

MR. BROCK: Yes, Your Honor. May I respond?

THE COURT: Yes.

MR. BROCK: Okay. First of all, in the disclosure.

(Off-the-record discussion.)

MR. BROCK: In the disclosure itself, when they describe the areas of testimony, that is not disclosed. In his five-page report, he does not disclose that he read the deposition of Melissa Guthrie. He says -- it says that he's read the deposition transcript of Dr. Metcalfe. Melissa Guthrie's deposition was taken the month before, his deposition report -- I'm sorry, his disclosure report. I'm not saying that in cases that experts get information that comes -- occurs later and they might consider it. And in his deposition, I think he did mention to be candid with the Court that he read the deposition, but he didn't -- in neither the deposition nor in the report is it gone on that he is going to testify that linking his opinion to the cause of death is what he read in her deposition and particularly the snoring that, you know, ties together with other physical findings.

What was disclosed, in essence, was, because he is a pain management specialist familiar with the toxicity and the level and the contraindications of use here and how it was not used and that, that in his medical opinion that that was the cause of his death. That is -- I have no objection to. Also, the comment that the Court made that, you know, because of his experience with other patients that subsequently died, but now

he's getting into the role more of a nondisclosed, you know, forensic pathologist area, which he may or may not be qualified to give that type of opinion, but that is not what he's been disclosed to give testimony on.

THE COURT: Well, and I --

MR. BROCK: So I --

THE COURT: I will say I -- I did think that his deposition said he was not an expert on the cause of death from the medical pathology standpoint.

MR. BROCK: Right.

THE COURT: All right. Let me -- let me hear from Mr. Pate.

MR. PATE: Well, a couple of points, Your Honor. I think, first, the deposition of Karen Guthrie is -- was taken after the date that his report was due to be disclosed. I think that's the first point I'll make. The second point is that I think this is an issue more as you indicated as to the basis -- that really goes to the basis of an opinion that he has disclosed and whether or not that was expounded upon subsequently in either the report or disclosure. The limine ruling that the Court as you just read talking about the mechanism of death that's what we're talking about.

THE COURT: I agree, but I'm dealing with an objection now. Okay. So, the objection now is that this is a surprise. I think you can resolve this by not referring to the

deposition testimony.

MR. PATE: If that's what it takes and he is fine. It's just--

THE COURT: And there must be certain aspects that you're wanting to ask him about, the snoring. And it seems to me that, again, still, basically, I'm being asked to decide did he disclose it, and I don't have the disclosure. I mean, I don't have the report. I don't think that you really want me to take the time to read through the entire deposition and the report when it's an easily -- to me, it's resolvable. If the objection is he didn't say he was relying on Ms. Guthrie's deposition to form his opinion --

MR. BROCK: I'm not objecting -- and I stand corrected. Her deposition was a day or two after that. He did in his deposition say he read her deposition. There's no surprise there. I'm not objecting to that.

THE COURT: And that he did consider it in forming his opinion?

MR. BROCK: I'm just going to assume that that -- I'm not going to deny that as the material that he said he relied upon.

THE COURT: All right. Well, Mr. Pate, I'm going to require you to ask him whatever specific thing in this deposition which for all I know lasted seven hours you're referring to, to make it clear. I think it's confusing. I'm

not saying that you can't ask him about the basis for his conclusion as to the cause of death. And I think that the basis of that opinion is going to go to the weight. And I'm going to allow cross-examination on it. So, frankly, I guess I'm -- I'm both overruling and sustaining the objection because I'm asking you to rephrase it to -- to -- so that it avoids the issue of any lack of disclosure, although, I'm still at a loss as to what exactly wasn't disclosed.

MR. PATE: I guess that's my question, too. I'm not sure if he testified that he reviewed her deposition as part of the opinions that he gave when he testified in his deposition. If he disclosed in his report subsequently that he was going to be offering opinion as to cause of death that he has knowledge and experience with the mechanism of death from opioid respiratory depression in other patients how is that testimony --

THE COURT: I'm going to hear the objection again so I can rule and we can move on.

MR. PATE: All right.

THE COURT: Please make as specific an objection as you can, what I recall the question was, what was the basis for your opinion, did it include Ms. Guthrie's deposition.

MR. BROCK: Well, then he went on to say did she make observations -- did you read in her deposition observations I think relative to his breathing near the time of his passing

and he's about to give opinions about what that meant to him and that was kind of the pending question. My objection is not that it was not disclosed that he read the deposition, and it's -- I'm not objecting that the Court has already ruled that he can give an opinion on the cause of death as it relates to a violation of the standard of care from his prior practice.

THE COURT: But not from his own limitations.

MR. BROCK: But as it relates to his interpretation of what she testified in her deposition as it relates to his opinion that the fentanyl patch was the cause of death, that has not -- was not disclosed as an area of testimony relative to a cause of death. And I'm -- I'm -- I have no ability to cross him on it.

THE COURT: All right. Well, as stated there, I'm going to overrule the objection, but he is -- he can talk about what observations he relied on, but I -- I don't know whether in somewhere in there in Ms. Guthrie's deposition there's objectionable material. So you're going to have to be specific as to what it is you're asking him.

MR. PATE: That's fine. I'm happy to do it. I don't like to lead too much and I think that to the extent I'm pointing out certain things I might be doing that.

THE COURT: Then there will be another objection and we'll handle it at that time.

MR. PATE: We'll handle it then, I guess. Okay.

THE COURT: Because it's not appropriate for you to lead this witness.

MR. PATE: Okay. I'll do my best.

THE COURT: Let's begin again.

(Brief pause.)

THE COURT: Mr. Pate, would you please rephrase and remind the witness of the question. And, Dr. Guthrie, you remain under oath.

MR. PATE: Yes. Thank you, Your Honor.

BY MR. PATE:

Q Dr. Grubb, are you ready to continue?

A Yes.

Q Okay. As a licensed pain medicine practitioner, are you familiar with the typical mechanism of death that ordinarily precedes a patient becoming unresponsive, stopping breathing and ultimately dying?

A Yes.

Q And what are some of the typical characteristics that you see in patients who in the hours prior to their death and even the minutes prior to their death, what are some of the typical characteristics that you see or that are observed in those moments leading up to a patient becoming unresponsive?

A Well, there are a variety of -- of appearances of what a patient looks like. And we'd also see it in a hospital

setting when someone's getting a lot of morphine or other opioids. It is very much -- very commonly associated with snoring, because the opioids are known to relax the muscles and the tissues in the soft palate in the throat so that snoring is a very common thing to see as the opioid toxicity gets greater and greater, there is usually a decrease in respiratory rate or at least a decrease in the amount of air flow. It may be manifested as shallow breaths, not necessarily slow but not deep either, so not getting enough oxygen. And then it gets to the point where there is such little air flow that the carbon dioxide level gets very high, what you're trying to exhale you're not exhaling enough if it's carbon dioxide and it can get to the point where you just stop. So, that's a very common typical presentation.

Q Are there any aspects of that presentation as you understand it that were exhibited by Donald Guthrie in the hours leading up to his death?

A Yes. In my reading of Ms. Guthrie's deposition testimony, she described how that during the night she would listen to him and even that following morning on a baby monitor and could hear the snoring. And I think, as I recall, she described it as loud snoring right up until the point where she stated that she didn't hear any more snoring. And that's when she went to check on him and found him unresponsive.

Q And is that something that is typical in -- is that the typical presentation of a patient prior to becoming unresponsive as a result of opioid toxicity?
A Yes.
Q And, of course, what does the package insert -- we've been talking about the package insert a lot. What does that insert say can happen if you prescribe these fentanyl patches in a manner inconsistent with the label?
A You can get respiratory depression and even death.
Q And similar with the FDA advisory we've talked about, Dear Doctor letter, what do those say can happen if fentanyl patches are prescribed in a manner inconsistent with the package insert?
A Death and respiratory depression.
Q And based on all of that, do you have an opinion as to what caused Mr. Guthrie's death in this case?
A Yes.
Q And what is that opinion?
A That he died of fatal respiratory depression as a result of the fentanyl toxicity in his bloodstream.
Q And do you hold that opinion to a reasonable degree of medical judgment?
A Yes.
Q Do you agree, Doctor, that just because a patient has an unexpectedly bad result that that does not mean the

doctor was negligent?
A Yes, I believe that.
Q In this case Donald Guthrie's death was clearly a bad result, right?
A That's right.
Q Okay. Do you believe Donald Guthrie's death, however, considering the course of treatment with Dr. Ball, was an unexpected result?
A No, not given the amount of fentanyl he was receiving. It was an expected result.
Q And in the interest of -- in the interest of disclosure, you've actually been hired by our law firm before to testify in cases involving fentanyl patches, right?
A Yes, that's right.
Q And some of those cases involve the adequacy of the warnings that are actually contained in the package insert, right?
A That's right.
Q And, of course, some of those cases, by contrast, have involved potential medical negligence claims of the kind that we're all here about today, pertaining to a prescribing physician. True?
A Yes, that's right.
Q How many cases would you say we have sent to you for purposes of just reviewing? Do you know?

A A little over a hundred, I would say.
Q And the percentage of those cases that we've sent to you, to your office for review, how many of those have you actually agreed to offer some kind of expert testimony in?
A Maybe a third or so of those.
Q Okay. So, it's fair to say that the majority of the cases that we have sent to you to review, you have not agreed to testify against another doctor. Is that fair to say?
A Yes.
Q And what kind of standard do you employ to the extent you can describe one that dictates your determination as to whether or not you are willing to serve as an expert against another doctor?
A Well, I mean, it's what I consider the reasonable standard of care threshold that I -- this is a very grave thing and I certainly hate the idea of doctors getting sued. And so, if I'm going to testify that a doctor's actions led to the death of someone, it's going to have to be of a very severe lapse in the standard of care. There's some gray areas in certain areas of health care, and I'm certainly not going to take an opinion against a doctor in a courtroom such as this one if it's gray.
Q Would you agree with me that allegations of medical negligence in a civil context, they're serious, aren't they?
A Yes, very.

Q And in light of their seriousness, do you take your obligations and the approach that you bring to serving as an expert in the case seriously?
A Yes.
Q And speaking of that, one last thing. You formulated some opinions in this case based on your review initially of the medical records pertaining to Donald Guthrie. Is that right?
A That's correct.
Q Okay. And you initially prepared a written report. Is that -- is that true that sort of articulated some of the opinions that you have?
A Yes.
Q Okay. And have the opinions that were expressed in that report -- essentially that we've been discussing today, are they essentially tracked in your report?
A Yes.
Q Okay. Had you read Dr. Ball's deposition -- you know Dr. Ball gave a deposition in this case, right?
A Yes.
Q Just like you, right?
A That's right.
Q And at the time that you prepared your report, delineating your opinions, had you been provided a copy of Dr. Ball's report?

A No, I had not.
Q Do you know if he had even been deposed?
A I had no idea that he had been deposed at that point.
Q Okay. And at the time you were deposed, you didn't have a copy of -- our office didn't provide you with a copy of Dr. Ball's deposition at that point, had we?
A No, they hadn't.
Q Have you subsequently read and reviewed his deposition and testimony?
A Yes.
Q And in so doing--
MR. BROCK: Your Honor, objection. That's clearly he's asked inquiry of an area that has never been disclosed. He had not read his deposition at the time we had a chance to depose him. Now, he's going to ask him questions about something he reviewed after we took his deposition not disclosed, that violates--
MR. PATE: I haven't asked him a question about any --
THE COURT: Let's wait for the question.
Okay. But, Dr. Grubb, if you'll pause before answering it to see if there is an objection to the question.
THE WITNESS: Okay.
BY MR. PATE:

Q Have you since your deposition had an opportunity to read and thoroughly review Dr. Ball's deposition?
A Yes.
Q Have you since had an opportunity to review any other depositions from other expert witnesses that have been taken in this case subsequent to your deposition?
A Yes.
Q Okay. Have your opinions changed--
MR. BROCK: Objection.
THE COURT: I'll allow him to answer that question.
BY MR. PATE:
Q Have your opinions changed in any way, Doctor, since reviewing Dr. Ball or any other expert's depositions in this case?
A No.
MR. PATE: Pass the witness.
THE COURT: Cross.

CROSS-EXAMINATION

BY MR. BROCK:
Q Good afternoon, Doctor.
A Good afternoon.
Q We've met before?
A Yes, we have.
Q I was at your deposition and took your deposition on June the 9th in your office, correct?

A That's correct.
Q All right. Let's start and go back to Exhibit J-4, which is March 18th, the last time that Dr. Ball's office saw -- saw Mr. Guthrie, correct?
A Yes.
Q And you were shown and has been admitted into evidence -- before I ask -- do you recall you were shown a portion about the pain he was having and things like that, and then you were giving opinions about, oh, the fatigue and the snoring, how that might represent some complications or side effects, correct?
A Yes.
Q I want to just go -- show the jury and ask -- go to the exhibit, Mr. Price, please. And I want you to go first to subjective. And, Mr. Price, if you'll highlight that.
This is the thing that was right above it that was not pointed out to you, and I asked you to read the subjective finding that was put on that date?
A "He feels that the Duragesic patch has helped more than anything else."
Q Okay. And then go ahead and read the rest of it so to completion?
A "The Dilaudid only makes him sleepy. Didn't help him sleep."
Q Okay. Now let's go up to the line above that on

March 18th, under chief complaint, because I will have some more questions. What was the chief complaint? The chief complaint is what's being related -- being relayed by the patient, correct?

A That's correct.

Q And what does it say?

A "Left knee pain, bilateral foot pain and bilateral ankle pain."

Q Bilateral would mean left and right pain on the foot and left and right pain to the ankle, correct?

A That's right.

Q Also -- and when you were asked those questions you were -- made a comment that he was showing fatigue. Do you remember you were asked that?

A Yes.

Q What's your recollection as an expert in this case the first time Mr. Guthrie related fatigue to Dr. Ball?

A As I recall, it was the first visit. I think he -- he admitted in this -- maybe in the review of systems section of the note or maybe the checked boxes he was checking on the intake sheet at Dr. Ball's office that he had fatigue as well.

Q So, one of the things you -- he relayed fatigue, did he not, each and every time he came to Dr. Ball's office, well before he ever got the fentanyl patch. Is that correct?

A That is correct.

Q Now, let's see if we can agree on a couple of things. I think we can agree I'm not going to change your mind in this case, correct?
A Correct.
Q Okay. And I think we do agree and you've said that this is a serious case?
A Yes.
Q And you understand you're the one and only person that this jury will hear about who says that Dr. Ball caused Mr. Guthrie's death --
A Yes.
Q -- by violating the standard of care, correct?
A Yes, that's correct.
Q Okay. And I think you would agree that being objective in a case is a very important concept, correct?
A Yes.
Q And you understand part of the jury's job is to evaluate your credibility, your credentials, what objectivity you bring to this process, correct?
A Yes.
Q You began your private practice in 2007, correct?
A Yes.
Q And at that point you had been working for about three years in a hospital setting before that, correct?
A Hospital and pain clinic setting in the three years

before that, yes.
Q All right. You began advertising on an Internet expert referral service in the first three years of your practice, correct?
A I don't think it's advertising, no. I think it's a directory where attorneys can call specifically for doctors who don't advertise. I think it says very clearly on the website we look for experts who are willing to testify on either side of a case and who don't advertise their services.
Q Well, maybe I misstated it. You allowed yourself in the first three years of your practice to let yourself be held out as a pain management expert through an Internet expert referral service, correct?
A Well, not in the first three years of my practice. The fourth and beyond years of my practice.
Q Well, what year was that, 2007?
A 2007, yes.
Q What year did you finish your residency?
A 2004.
Q So, is that the first three years?
A No. I didn't start using -- I didn't start reviewing cases as a medical consultant until 2007. I didn't do any of that between 2004 and 2007.
Q We agree. You got out of residency in 2004. And then in 2007, in that three-year period, you began to say, I'm

allowing myself to be known as an expert in pain management consultant through an Internet referral service, correct?
A I guess I don't understand the question. I'm hearing you say that during these three years I held myself out to be an expert.
Q No --
A That's not what you're saying?
Q Beginning in 2007?
A Yes. That's correct.
Q And that's how Mr. Miller found you, correct?
A Yes, to my knowledge, that is how he found me.
Q And you were asked a little bit of questions about that, but a hundred cases for Mr. Miller's firm in the last seven years, correct?
A That's right.
Q Almost all of them involved the fentanyl patch, correct?
A That's right.
Q In fact, of all the cases you reviewed, up to 90 percent have been for Mr. Miller, correct?
A That's approximately right, that's right.
Q Approximate to your own testimony?
A It's about 80 -- 85 to 90 percent, that's right.
Q And you have earned 150,000 to $200,000 testifying in fentanyl patch cases, correct?

A Sure, over the last seven years or so, that's right.
Q You have never given a deposition on behalf of a defendant like Dr. Grubb, correct?
A That's correct.
Q The only depositions you've given on behalf -- are on behalf of the plaintiff, correct?
A That's right.
Q And we talk about testifying, at least from the list you disclosed to us, in the last four years you've never testified on behalf -- at trial for a defendant, correct?
A Correct.
Q And if we actually go back and look at -- when we took your deposition, you've never even been disclosed as an expert to testify on behalf of a physician met the standard of care, correct?
A That's correct.
Q In fact, in all the years that you've been acting as a retained paid consultant, that's what you are, correct?
A That's right.
Q You've never been disclosed or given any written report that says a physician met the standard of care, correct?
A That's correct.
Q Now, as to why -- do you recall when we met I asked you why did you become -- allow yourself to be listed on an

internet expert referral service. Do you recall we had that conversation?
A Yes, I do.
Q And it would be your position that you talked to some of your colleagues, your partners, and they said this is a good way to become a better doctor, correct?
A That's right.
Q But then I also asked you, I said, it's also to supplement your income, correct?
A That's right.
Q So, it's 500 an hour for deposition, correct?
A That's right.
Q Two thousand a minimum day for trial testimony, correct?
A That's right.
Q $350 an hour to review records, right?
A That's right.
Q So, let's look at your first invoice, which is Exhibit J-62.
MR. BROCK: We would move into evidence. There's no objection on J-62.
MR. PATE: No objection.
THE COURT: It will be admitted.
(Joint Exhibit 62 was received into evidence.)
BY MR. BROCK:

Q So -- and, Mr. Price, will you highlight "review medical records"?

So you spent an hour and a half reviewing medical records on February 7, 2011. That's your first work in the case, correct?

A That's correct.

Q And in an hour and a half you determined that in your opinion Dr. Ball caused the death of Mr. Guthrie, correct?

A That's correct.

Q What medical records did you review on that day?

A I don't recall exactly which records.

Q Well, you know, in the concept, Doctor, that, you know, again, you're testifying, you're at $2000 a day, right?

A That's right.

Q And you said attention to detail is important, correct?

A That's right.

Q I'd like you to explain to the jury what records you reviewed and did not review on that day?

A Well, without having all of these records in front of me, which I didn't bring this week, this was three and a half -- over three and a half years ago, I don't remember exactly which records. From what I recall, maybe, I guess, Dr. Ball's clinical record, maybe the autopsy report. That

would be my best guess, but I will acknowledge I don't have a perfect memory. It's been three and a half years.

Q That's a guess?

A That's -- that is right, that's an estimation.

Q And then after that you reviewed and signed certificates of merit saying there's a basis for proceeding in this case. Is that correct?

A That's correct.

Q Before you arrived at -- after an hour and a half, did you pick up the phone and call the medical examiner and say I'd like to get some more information?

A No.

Q Did you ask to have -- you couldn't have access to Dr. Ball at that point. We'd agree on that, correct?

A Correct.

Q He doesn't even know you're looking at it at that point, correct?

A That's right.

Q Did you ask to speak to Ms. Guthrie who is the client of Mr. Miller whose firm had retained you?

A No, I have no -- I have a policy against speaking with clients.

Q Well, you did say you read her deposition, right?

A That's right.

Q You said none of those things changed your opinion,

correct?
A That's correct.
Q So, before you determined that Dr. Ball caused the death of this gentleman, did you call her up and say what did you observe, did he have any complications during the 18 days, what was the degree of his pain, did you take advantage of that opportunity through Mr. Miller to find out any information from Ms. Guthrie?
A Well, the risk of doing that would outweigh, first, the risk of not being objective. That's the reason I didn't do it is I would have loved to have talked to her, but I know that talking to someone who's just lost their husband my bias me in an inappropriate way and that's the highest priority for me.
Q But you read the deposition?
A That's correct.
Q And how many years was it since the passing of her spouse?
A At the time of her deposition?
Q No, at the time that you were reviewing this.
A I guess about a year or so.
Q All right. So, it wasn't immediately after his passing, even though it was still within about a year, correct?
A That's correct.

Q Now, let's go to your next invoice of 1/6/11. All right. Now, will you highlight, Mr. Price, all the things reviewed?

Now, you have reviewed -- spent considerable more time reviewing things before you draft your report, correct?

A That's right.

Q 4.5 hours, 3.5, 1.5, .5, .5. And the deposition of Dr. Metcalfe, correct?

A That's right.

Q And so, we're looking at 10 hours --

A That's correct.

Q -- correct? So, you did this now -- it was an hour and a half to determine, now you've read an additional 10 hours and you now write a report. Is that correct?

A That's right.

Q Let me go back for a second. Let's go back when we were talking about -- even though -- even though you have worked with this firm for almost all your legal work and almost all your cases are on behalf of the plaintiff, you feel that you are completely objective, correct?

A That's right.

Q All right. Let's go to your list of depositions that you have given and that was part of your disclosure, which is a part of J-62. Do you remember in this deposition we went through this list?

A Yes.
Q All right. Let's go to the first one in April of 2010. *Grange versus Mylan*, you were saying that the patch was defective, correct?
A No. That was not what I was saying.
Q Or the warning?
A I was saying the warning at that time was inadequate.
Q All right. Was that a case against a physician?
A Not to my knowledge.
Q Okay. How about the next one? Can you highlight that, please? Was that a similar allegation?
A Yes.
Q Next one?
A Yes.
Q Next one? I'm sorry, Walter versus -- *Richardson versus Mylan, Pope versus Mylan*, same allegation?
A Yes.
Q Warnings are inadequate?
A That's right.
Q *Woodcock versus Mylan*, against the manufacturer?
A That's right.
Q If we go through all 13 except the last one, in each of these cases, you were saying that the manufacturer was -- warning was inadequate and part of the cause of death of the

person in that case, correct?
A No. Actually, I think about half of those were. The other half were me being designated as an expert witness for standard of care.
Q Okay.
A I only recall maybe half of those being warnings.
Q So, half of them -- everyone that I see through the 13, if you look at the list, they start with Alza, Alza or Mylan. Those are patch manufacturers, correct?
A That's true, but I think there was also in some of those cases a doctor as a defendant.
Q So, there were cases where you were criticizing both the manufacturer and the physician. Is that correct?
A In those specific cases where it was -- where there may have been substandard care, I don't recall whether I was also asked about the adequacy of the labeling. I may have been. I just don't recall.
Q And while you do not think it played a role in this case, the label, correct?
A Correct.
Q You think that the label as put out by the manufacturer at the time that Dr. Ball prescribed it was inadequate, correct?
A Yes, in a very small part.
Q All right. Now, you agree there's no medical

textbook saying that you cannot prescribe a fentanyl patch outside the black box warning?

A I don't agree with that. I'm sure there are textbooks that talk about black box warning and conformity to it.

Q Can you address -- when I asked you in your deposition to please identify a textbook, journal, or article that says you cannot prescribe a fentanyl patch outside the black box warning you said that you could not identify such a text or journal, correct?

A That's true, but that's not the question you asked. You asked are there textbooks -- is it true that there are no textbooks -- I don't remember exactly what the question was -- and I am assuming there are, I just don't know of any specific ones to give you today.

Q Now, we heard -- the jury did hear that you do prescribe the fentanyl patch -- I've forgotten what was the number of times?

A About 200 patients.

Q And I know you're critical and I'm not going to change your opinions about Dr. Ball. But when you prescribe the fentanyl patch, what is -- two weeks is the time you actually ask them to come back for a follow-up, correct?

A That's correct.

Q All right. And then after two weeks on this patch,

you say they don't need to come back for another month usually, correct?
A Depending on the circumstances, but, in general, if there are no problems, yes.
Q And, by the way, in that two weeks, I would assume that you would instruct your patients or if they're spouses was attending them, if they're noticing unusual signs of respiratory depression or unusually sleepy that they should call you immediately, correct?
A That's right.
Q Any indication that Dr. Ball was ever contacted during the 14 days that he was on the 50 microgram patch?
A No.
Q Was there any time that Dr. Ball was contacted when he was on the 75 microgram patch?
A No.
Q Did -- in your review of the deposition of Ms. Guthrie, did she ever say in that 14 days that she ever had a -- that her husband ever expressed a concern about complications or side effects from the patch?
A Not that I recall.
Q During the four days that he was on the 75-milligram patch, did Ms. Guthrie relay that her husband ever related concern or complications from the patch?
A Not that I recall.

Q Not that I recall or well--
A From what I recall of her deposition testimony she did not mention anything about that.
Q Okay. Now, going to Ms. Guthrie, Ms. Guthrie was very involved in his care, correct?
A From what I can tell, yes.
Q She was very concerned, she was attentive, she helped put on the patches, helped take off the patches, tried to keep him to take the medication, correct?
A That's right.
Q Did Ms. Guthrie in her deposition say that she observed any complications that concerned her enough that she wanted to contact the doctor's office?
A No.
Q During the four days -- the 14 days before the patch was moved to 75, did she ever observe -- have any concerns or complaints about side effects that she contacted the doctor or wanted him to contact the doctor to share her concerns?
A No.
Q During the 18 days that he was on the patch, was -- was Mr. Guthrie ever examined by someone other than his office for his overall status?
A Not that I recall.
Q Okay. Did you review the records of where he was pre-op, did a preoperative physical prior to surgery on the

23rd?
A Yes.
Q Where was that?
A From what I recall, he was evaluated on the 23rd, the day of surgery. And there may have been another visit just prior to that for -- to make sure lab tests were -- were done and that kind of thing for surgery.
Q Well, knowing that attention to detail is important, if his -- if during by other means his respiratory status or he was given a physical exam during that let's say the 14 day period that he was on the patch, that might give you insight to how he was doing, correct?
A It might except, again, he was awake at those times, not sleeping.
Q But it might give you some assessment?
A Sure.
Q So, did you review it?
A Yes.
Q When was it done?
A I don't recall. I'd have to have the stack of records in front of me to flip through them. There is quite a lot of records.
Q Well, as best you recall, it was shortly, like a day or two before?
A Yes.

Q So, you're not aware that it may have been done as early as March 10th or 12th?
A Well, it certainly was done sometime between March 1st and March 23rd, because March 1st is the day that Dr. Ballard, orthopedic surgeon, posted him -- or intended to post him for surgery.
Q Now, I think you have agreed and you agree in your -- you said in your direct testimony and we talked about it in your deposition that you agree and it's been your -- your experience that medical judgment is important in pain management practice, correct?
A In general, yes.
Q And you certainly have had disagreements with anesthesiologists about what drug to prescribe?
A Occasionally. Not -- not different categories of drugs, but within a certain category of drug, certainly.
Q Doctor, do you recall me asking you that question? You agree that you've had disagreements with anesthesiologists about what medication to give, correct?
A Yes, but we had quite an argument about what that meant. That meant, like, within a certain range of standard of care medications, not between an opioid and Tylenol, let's say.
Q Well, this isn't a case about opiate versus Tylenol, correct?

A It is a little bit.
Q Well, but, no, you haven't gotten here -- have you mentioned the word Tylenol today?
A Yes, I mentioned acetaminophen earlier.
Q No, but did you mention it relative to Dr. Ball prescribing Tylenol?
A I think he did prescribe Tylenol, in the form of Percocet.
Q Percocet is an opiate, correct?
A Sure, with Tylenol as well.
Q It has an element of it.
A Sure. It reduces the amount of opioid necessary to give pain relief when you use Tylenol with it.
Q Now, you're an advocate of board certification, correct?
A Yes.
Q And that requires additional experience and training in pain management, correct?
A Yes.
Q And you are board certified?
A Yes.
Q And Dr. Ball is board certified, correct?
A Yes.
Q And you agree that he is an experienced pain management specialist, correct?

A Yes.
Q Now, Doctor, you have had patients that have had bad outcomes, correct?
A Yes.
Q But, according to you, it's absolutely correct that the fact that your patients have had a bad outcome doesn't mean that you violated the standard of care, correct?
A That's correct.
Q And in every case you've been involved in involving a physician, there's been an expert who has reviewed the same information and has -- at least you're familiar that they say that the physician did not violate the standard of care, correct?
A Yes.
Q But you believe that they're wrong and you're right, correct?
A In those specific cases, yes.
Q You agree education and training is a part of that -- part of what you need to bring to the table, correct?
A Yes.
Q Now, you did mention -- you used the word -- we talked about -- you talked about off label earlier, right?
A Yes.
Q Off label is the concept where a physician can prescribe different than what the FDA-issued instructions say,

correct?
A That's correct.
Q And, in your own words, the definition of "off label" means prescribing medications not in accordance strictly within the labeling of the product, correct?
A That's right.
Q I looked up -- so you used the word strictly, correct?
A That's right.
Q And strictly, you'd agree, means "rigorously conforming"?
A Yes.
Q And in those instances you have had occasions where you have prescribed, did not follow the rigorous requirements, and have determined that it was appropriate or acceptable to prescribe off label?
A That's actually a mischaracterization. The strictly is meaning the entirety of the labeling, strictly meaning I would have to abide by every bit of it to not prescribe off label. You're implying that the strictly means that the labeling itself is super strict and rigorous. And those would be the exact kind of labels and the parts of labels that I might would not adhere to for a certain patient.
Q Well, let's put a finer point on it. You have prescribed medication that is contraindicated according to the

labeling instruction, correct?
A At times, for non-opioids, yes.
Q Okay. But contraindicated-- Remember earlier today you were taken through it's contraindicated in the black box, don't do it.
A That's right.
Q You have on occasion prescribed medication that is contraindicated, correct?
A Only when it's not a black box warning, yes.
Q All right. Well, there's parts --
A There's a difference.
Q Well, I know you think that --
A FDA says there's a difference.
Q We agree to disagree. But the point is, there are -- without black box warnings, there are contraindications and a whole host of medications that are prescribed that can have -- say, "This can lead to death," correct?
A That's true.
Q Including other opiates, correct?
A That's true.
Q Now, when you -- you gave an example -- when you've done black box prescribing -- I'm sorry, when you have done off-label for a contraindicated use, it's one where you say, "The FDA hasn't studied that, and I feel that from my education, experience, and training, that it's safe to use

even though the FDA says, 'Don't use it for this purpose,'" correct?

A That's correct.

Q Now, you've talked about chronic pain a fair amount, you were asked a lot of questions about this is chronic pain, and you thought this was acute pain, correct?

A That's correct.

Q And you said that six months or more is when you personally think that chronic pain begins, correct?

A That's one of the definitions. That's not the one I adhere to the most. There's another definition that would be pain that exceeds the duration of expected healing of a particular condition, and that's the one I usually adhere to the most.

Q But you have read textbooks and journal articles and guidelines that use the range as early as three months, correct?

A That's true. There are some that say three to six months.

Q So you are disagreeing with that, or you're saying there's a range of interpretation of what chronic pain can be?

A There is somewhat of a gray area of what constitutes chronic pain or when acute pain turns into chronic pain.

Q And in some definitions it can begin as early as three months?

A In some definitions, yes.
Q But that's not your personal definition?
A That's correct.
Q Now, what's your understanding, from your review of the medical records, the first report of when Mr. Guthrie was having pain in his legs?
A I don't recall there being-- I think there may have been in his primary care records back in '07, '08 where he had some mild pain not requiring heavy-duty drugs. And I think he took Skelaxin, which is a muscle relaxant, for some leg discomfort maybe a year or so before his death. So I think there was -- I would have to say as early as maybe '07. '02 he had an injury where a Coke machine fell on his leg, I believe, in '02, so I'm sure his medical record reflects some leg pain in '02.
Q When did -- from your review as an expert witness in this case, when did Dr. Dorizas say that -- as related to the patient to him, that the pain began?
A I think he said approximately three months prior to when Mr. Guthrie presented to him.
Q And when did he present to Dr. Dorizas?
A I believe in November of 20 -- 2009. I'll have to look through my records.
Q It is November. I'll -- I'll save that.
A Okay.

Q So assuming it's November of 2009, what is three months before November of 2009?
A So three months before November 20th would be August 20th.
Q All right. And how many -- how many months would have occurred from -- at the time he first presented from August 20th, 2009, to Dr. Ball, how long would that have been?
A A little less than three months, four months.
Q August to December?
A August, September, October, November, three and a half months, I guess.
Q Okay. And how about by the time he first was prescribed the patch, how much time had elapsed?
A That would have been March 4th. So September 20th, October 20th, November 20th, December 20th, January 20th, February 20th, just over six months.
Q Thank you. You said that you've read some additional depositions, correct?
A Yes.
Q You didn't change your opinion, correct?
A Correct.
Q Dr. Johnson testified that it was chronic pain, correct?
A I believe he did, yes.
Q Dr. Kasser testified it was chronic pain, correct?

A That's right.
Q Dr. Hart testified it was chronic pain, correct?
A Yes.
Q Dr. Ball's-- Dr. Ball testified it was chronic pain, correct?
A That's right.
Q Let's look at--
(Off-the-record discussion.)
MR. BROCK: I'm going to refer to Exhibit J-51, which are the records of Dr. Dorizas, if there's no objection.
MR. PATE: No objection.
THE COURT: Be admitted without objection.
(Joint Exhibit 51 was received into evidence.)
BY MR. BROCK:
Q Look--
Mr. Price, if you'll turn to the initial visit on November 20th. Would you highlight the sentence, "A 48-year-old," through "insidious onset with gradual progression," all the way through the sentence.
All right. So this is what we've just been talking about, correct?
A Yes.
Q And then at the end of the paragraph he recently had--
Can you highlight that last sentence? I'm sorry.

Let's go up, please. Now let's go to the next sentence.

It says, "He complains of extreme pain on the medial anterior aspect of his left --"

Go to the second sentence, Mr. Price, please.

Would you read the second sentence for us on the monitor, Doctor, please?

A Yes. "He complains of extreme pain on the medial and anterior aspects of his left knee that limits his ability to walk."

Q All right. Would you continue to read the paragraph, please?

A Yes. "He has extreme hypersensitivity of even the skin over his leg. He cannot stand for even the covers of his bed to touch it at night. The pain does not appear to be activity-related. He has started using assistive devices for ambulation due to the pain. He additionally has some pain in the right lower extremity but not to the degree of the left side. He complains of swelling in both of his lower extremities. He has been using Lortab as prescribed by his primary physician, but this has not touched the pain. He also -- he has also used some Indocin prescribed by Dr. Sherwood, but discontinued this. He recently had an MRI of his knee, which showed a meniscus tear."

Q So in the entirety of this, he's complaining of pain in both the left and right leg, correct?

A That's right.
Q He's explaining that the sheets of the bed cause pain, correct?
A That's right.
Q He describes extreme pain, does he not?
A That's right.
Q He uses Lortab. Is that correct?
A Yes.
Q And Lortab, is that an opiate?
A Yes, it is.
Q Okay. And this opiate that he was prescribed, how did Mr. Guthrie say how it worked for him?
A According to Dr. Dorizas, it did not touch the pain.
Q Well, when you say "according to Dr. Dorizas," you would assume that this is the information that Mr. Guthrie told Dr. Dorizas, correct?
A Yes, or some variation of it. I think Dr. -- I think Mr. Guthrie had mentioned that the Lortab helped a little in a different set of medical records. I think it's a little bit of a gray area there.
MR. BROCK: So let's -- let's turn to the assessment, please, Mr. Price. Highlight it, please.
BY MR. BROCK:
Q So Dr. Dorizas is an orthopedic surgeon, as we've discussed, correct?

A That's right.
Q And his assessment were -- in terms of primary diagnosis was what?
A "Reflex sympathetic dystrophy of lower limb."
Q And with-- Continue on.
A "Idiopathic peripheral neuropathy."
Q "Primary." I'm sorry. You missed part of it. "Primary," and then follow --
A Oh, "Primary," sure, "Complex regional pain syndrome."
Q All right. Second? I'm sorry. Can that cause pain, that condition?
A Yes.
Q Next one?
A "Idiopathic peripheral neuropathy not otherwise specified, NOS, bilateral lower extremities."
Q Okay. What does "idiopathic" mean?
A It means that the cause is unknown.
Q All right. And it's relating to both legs, correct?
A That's right.
Q Then we also have the derangement of the posterior horn of the medial meniscus, correct?
A That's right.
Q That can cause pain, correct?
A Yes.

Q And the fourth assessment is "venous insufficiency NOS --"
A That's right.
Q "-- bilateral lower extremity"?
A Yes. And that can cause pain, too.
Q All right. So all four of those conditions and assessments can cause pain, correct?
A That's true.
Q All four of those can cause pain that require medication, correct?
A That's true.
Q All four of those can require trying different things, from TENS unit to Skelaxin to analgesics to even opiates, correct?
A That's true.
Q Now, from your review of the case, when did he next see Mr. Guthrie, if at all?
A You're asking about Mr. -- about Dr. Dorizas?
Q Right.
A I'm not sure he saw him again prior to him seeing Dr. Ball.
Q Is that your testimony?
A Again, I-- This is a huge amount of medical records. I'm happy to sit and go through someone's stack of them to look to see if there's any-- I don't have it in front

of me. I have Dr. Ball's records in front of me. So I'm looking at Dr. Dorizas' records that he sent to Dr. Ball, but I don't have it in front of me.

Q Right. Part of -- part of Dr. Ball's chart is this November 20th record, correct?

A That's right.

Q Were you ever provided the rest of his records from Mr. Miller for the other times he saw -- saw Mr. Guthrie that are not part of Dr. Ball's records?

A Yes, I have reviewed that.

Q Okay. Well, then when did he see him, and what did he determine --

A Again, I reviewed it. I didn't know this was a memory contest here. I can bring maybe a whole box of records up here and flip through them, and you can hand me maybe the folder that has Dr. Dorizas' records. But as you said before, my invoice showed about ten hours. It was in the midst of those ten hours. I don't recall what other dates he was seen by Dr. Dorizas.

Q Well, I mean, part of what you're-- I think you told the jury that while he was seeing Dr. Ball, he didn't even get close to what you consider as RSD.

A That's correct.

Q All right. And what I'm asking you is, did any other treating physician, if you know, also come to the

assessment, while he was treating with Dr. Ball, whether he had RSD? Yes, or no?
A Well, clearly Dr. Dorizas gave him a diagnosis of RSD, too, and that's why he sent him specifically to be evaluated as to whether this is-- He sent -- he sent Mr. Guthrie to Mr. Ball to get a firm diagnosis. I think Mr. Dorizas even said in his referral, "Please evaluate and do these blocks." And he's asking, "Please, Dr. Ball, you're the expert in RSD, not me. Please tell us whether this is RSD."
Q Well, he didn't-- Where does it say, "I'm not an expert on RSD, and you're not"?
A Well, no, that's why he sent him -- that's clearly why he sent him to Dr. Ball, because he didn't know, "Is this the meniscal tear that's causing all of the knee pain, or is this RSD? Dr. Ball would be able to tell us."
Q Are you saying that an orthopedic surgeon cannot make a diagnosis of RSD?
A He-- It depends on the orthopedic surgeon. I work with a lot of orthopedic surgeons that do not make the diagnosis of RSD.
Q What about this doctor? Did he make -- make a diagnosis of RSD?
A He included it in a list of four things, as you mentioned, that could be possibilities of causing the knee pain, and he admitted he had no idea which part of it was the

source of his plain. That's why he sent him to Dr. Ball as the pain expert.

Q So my question, again, is, what -- from your review and your charging of the time in this case, what did Dr. Dorizas find when he -- if he saw Mr. Guthrie again at the same time Dr. Ball was treating him, if you know, if you remember?

A Well, I don't remember, as I sit here today, an independent recollection of a specific note in one of the two dozen or so office records I've reviewed. If you'd give me the pleasure of showing me the records from Dr. Dorizas' office, I'll be happy to tell you. I don't remember exactly.

Q Well, what do you recall about, for example, whether Mr. Guthrie was able to persist with physical therapy?

MR. PATE: Your Honor, I'm would object. If there's going to be continuing questions about records Mr. Brock is not willing to show to the expert, then I think that's inappropriate.

THE COURT: Do you have a rule of evidence you're basing that objection on?

MR. PATE: I'm sorry, Your Honor?

THE COURT: Do you have a rule of evidence that you're basing that objection on?

MR. PATE: None come to mind. I think that if he's going to ask him questions about a specific record, though,

that he should be allowed to show him -- that he should be allowed to look at and evaluate that record, instead of asking him questions about records he's not showing him. That's the basis of my objection.

MR. BROCK: Do I get to respond? May I respond?

THE COURT: Yes.

MR. BROCK: He has not cited a rule of evidence.

THE COURT: Well, Doctor, if you can't remember something without the record, you can so state, and if a lawyer chooses to show you a record, you can look at it.

THE WITNESS: Okay.

THE COURT: So I'm going to overrule the objection.

BY MR. BROCK:

Q Because, again, we've agreed early on this is a serious case and attention to detail is important.

A That's true.

Q That's why -- that's why I'm trying to understand what facts you do recall and what facts you may recall. May be important or not, but that's for the jury to decide. Okay?

A Okay. Since Dr. Ball prescribed the patch here, I'm saying the detail needs to be on his record and what he believed the diagnosis was and how he came to that diagnosis. And I'm happy to look at other records that you would put before me, but I don't recall other records.

Q Well, you spent almost ten hours looking at other

medical records and charging $350 an hour to help you write your report, correct?
A That's correct, about a year ago.
Q Right. And you used that-- And those records included Dr. Sherwood, his family doctor, correct?
A That's right.
Q Including at least Dr. Dorizas in 2009, correct?
A That's right.
Q So you did take the time to include that in your evaluation?
A Absolutely.
Q So let's go back to Dr. Dorizas. All right. Let me show you his record of -- from the same -- already admitted as an exhibit, his exam of January 18, 2010. By the way, from your review of the records, do you recall anything else that occurred on January 18, 2010?
A I believe that may have been one of the -- I can look in Dr. Ball's records -- one of the times when he got an injection from Dr. Ball, a lumbar sympathetic block.
Q If I were to relay to you that that injection was done between 7:45 and 8:00 a.m., would you have any reason to disagree with that time frame?
A Not without having the records in front of me.
Q Is it reasonable to assume that he went to see Dr. Dorizas after that injection?

A I don't know. I would have to see the time stamp on Dr. Dorizas' records and the time stamp on Dr. Ball's records.
Q Okay. Anyway, so at this point it says, "48-year-old male presents with complaint of pain which has improved since his last visit," correct?
A Yes.
Q And then it says, "He reports that he saw a neurologist who confirmed that he has severe neuropathy in his left lower extremity and mild in his right lower extremity," correct?
A That's right.
Q And his report is that he recently had Injection Number 2 of 3 performed by Dr. Ball, correct?
A That's right.
Q Does that answer the question which came first?
A Yes, it does, because -- I'm just verifying with Dr. Ball's records that the third one was some date after the 18th. I don't know, the third one might have been on the 18th. December 16th, January 18th -- and the records I have here only have records of two lumbar sympathetic blocks, but I know there was a third one, so...
Q I'll represent to you this was the second one. Does that seem reasonable?
A Yes, it does.
Q So if that was the date of his second one, then he

says he's recently had the second one, that would probably be preceding him seeing the doctor that same day?
A Same day.
Q And his leg is improved, correct?
A That's right.
Q On that day when he went in to see -- and got that -- the block with the fentanyl, his pain was 5 beforehand, correct?
A That's right.
Q And it was zero afterwards, correct?
A That's right.
Q But the relief from the injections that Dr. Ball gave did not -- did not last, as according to the records, correct?
A That's correct.
Q Then it goes on to say, "He was unable to fill his prescription for topical NSAIDs due to financial reasons." We're certainly not attributing any ill reason not to do that, but that's what it reports, correct?
A Yes.
Q What's tropical NSIADs? I'm sorry, not "tropical." We probably all want to be in the tropics, but topics.
A It's topical cream, gel, that's in antiinflammatory medication such as Motrin.
Q Okay. And that times is a modality to treat pain,

correct?
A It is, yes.
Q And then it goes on, "He was unable to continue with physical therapy due to financial reasons," correct?
A That's right.
Q And then it goes on, "He denies any locking or catching sensation. He continues to have mild to moderate residual left lower extremity discomfort," correct?
A That's right.
Q And in fact we did see over time the pain went from a 4 to 5 all the way up to 8 over the last visits, correct?
A That's right.
Q So let's go to -- finally to the back -- back part, please, to the assessment. "Assessment," and this is in the time frame -- do you remember we just talked earlier ago -- you're saying that this case, according to you, did not get close to RSD anytime that Dr. Ball was seeing him, correct?
A That is correct.
Q And this is an examination by an orthopedic surgeon who is seeing him on the very -- it turns out not only at the same time, on the same day that Dr. Ball gave him an injection, correct?
A That's right.
Q So what does the very first assessment on that same day that Dr. Ball -- in which you say, according to you, did

not ever get close to RSD, what was Dr. Dorizas' assessment?
A "Reflex sympathetic dystrophy of lower limb."
Q What else does it say?
A "Primary: Regional complex pain syndrome."
Q What else does it say in terms of these -- again --
A The same ones.
Q Same ones. All four of which can cause pain, correct?
A That's right.
Q Now, let's go now to the treatment, which is right below that. "Patient reports he's doing much better," correct?
A Yes.
Q And we know he's just come from the doctor's office where his pain's gone from a 5 out of 10 to a zero, correct?
A That's right.
Q Improved significantly, correct?
A I'm assuming he means not just today.
Q Fair enough. Improved. "Counseling done, and conditions discussed with patient," correct?
A Yes.
Q And then it goes on, and will you read the next sentence, "I explained"?
A "I explained to the patient and his wife that he desperately needs to continue with the home therapy program or

return to physical therapy."
Q Do you have any indication that he returned to physical therapy?
A No.
Q Now, let's go-- What-- An orthopedic surgeon treats knee injuries such as a torn meniscus, correct?
A That's right.
Q And what does Dr. Dorizas, the orthopedic surgeon who made the diagnosis, say in the next sentence, "I have explained"? Start with "I have explained."
A "I have explained to the patient --" oh, "I've explained that I do not believe his medial meniscus is symptomatic."
Q Okay. So does that mean that Dr. Dorizas, the orthopedic surgeon, who is an expert in treating knee injuries, does not think that the medial meniscus is symptomatic?
A That is true.
Q And then what does he go on to say?
A "Additionally I believe surgical treatment of his meniscus, with his current pain, swelling, and hypersensitivity, would be a huge setback for him."
Q Okay. So this doctor, Dr. Dorizas, on January 18th, is basically saying, in so many words, "I don't think the medial meniscus attributes for all the pain you're having, and

going forward with the surgery at this time could be a huge setback for you," correct?

A That's what he believed, that's right.

Q And he's also desperately begging Mr. Guthrie, "I know it's -- you've got tough financial circumstances, but at least do home therapy or try to get back to physical therapy," correct?

A That's right.

Q Thank you. Did Dr. Ball, prior to the ordering of the patch, order anything relative to help with the desensitation -- desensitization?

A Will you repeat the question, please?

Q Can we go back to it, please?

That's all right. We'll move on.

We're getting there. Now, yesterday the jury heard a series of questions about whether Dr. Ball contacted the FDA or didn't contact the FDA. But certainly you've done dozens and dozens and dozens and dozens of cases involving about what you feel was the inadequacy of the warning, correct?

A That's right.

Q You've never contacted the FDA, correct?

A Not directly, no.

Q All right. You've never written a letter to the FDA, correct?

A Not directly, no.

Q You've never given a peer-reviewed paper about the FDA -- inadequacy of their warning, have you?
A No.
Q Now, you made reference today about a study of Dr. Rankin about -- where he was studied -- where he performed a sleeping test for Mr. Guthrie, correct?
A That's right.
Q Did he prescribe surgery to help correct that condition?
A No.
Q What's the most common thing, if you have a serious sleep obstruction, that people are more commonly prescribed?
A C-PAP, if you do have sleep apnea, which was not diagnosed at that time.
Q And he was not prescribed a sleep -- a C-PAP machine, correct?
A That's right. He did not have sleep apnea at that time.
Q So the only thing they really prescribed was to put Breathe Right strips on his nose?
A That's right, and avoid sedative medications.
Q And avoid driving. But in terms of affirmative actions in terms of a condition where the -- if the doctor had been more -- if Dr. Rankin had been more concerned about the depth or extent of the sleep studies, whatever they revealed,

if he had wanted to go to a more serious level and had a more serious concern, he would have likely prescribed him on a C-PAP machine at that time, correct?

A Yes, if he had had sleep apnea at that time, I'm sure he would have recommended that.

Q Some things I think we might be able to agree on. I think you've already said, but I want to make sure it's clear, Demerol is a potent narcotic, correct? You agree that it's a --

A It's a narcotic. It's less potent than morphine, but it's a narcotic.

Q A moment ago you just said that Mr. Guthrie was not diagnosed with sleep apnea at that time. Do you recall that?

A That's correct.

Q Was he ever diagnosed with sleep apnea?

A No.

Q You agree Demerol is a potent narcotic. True?

A I agree that it is a narcotic.

Q All right.

A It's not potent. I mean, morphine is considered not real potent itself. And Demerol is less potent even than morphine. So it's not considered a potent one on a weight basis, milligram versus microgram, but it's a narcotic.

Q Well, I'm glad you mentioned that, because one of the things that's been talked about is how powerful fentanyl

is, correct?
A That's right.
Q By weight?
A That's correct. That's the definition of potency, is by weight.
Q Right. Right. And it's given in what terms of measurement that they talk about?
A Tiny, tiny micrograms, right.
Q It's micrograms?
A Micrograms, as opposed to milligram, which is a bigger number.
Q So it is, by weight, much more powerful?
A That's right.
Q The jury has heard the terms 80 to a hundred times more powerful.
A That's correct.
Q But it's not prescribed in equivalents of the things that are prescribed in milligrams, correct?
A That's correct.
Q So when-- That patch is in micrograms, not milligrams, correct?
A That's right.
Q Can Demerol cause respiratory depression?
A Yes.
Q You agree with that?

A Yes.
Q And Mr. Guthrie received Demerol post-op after his knee surgery, correct?
A Yes, a small dose.
Q It was present -- at least present in his autopsy report, correct?
A That's right.
Q He was also given Percocet while he was in the hospital. Is that correct?
A That's right. I think one.
Q Percocet's a narcotic, correct?
A Yes, it is.
Q Percocet can cause respiratory depression, correct?
A It could, in high enough doses, most definitely.
Q Can Ambien cause respiratory depression?
A By itself, not to my knowledge. In combination with opioids, it could.
Q Now, the surgeon also injected morphine into Mr. Guthrie's knee during the surgery, correct?
A That's right.
Q As an anesthesiologist -- that's your background, correct?
A That's right.
Q So is Dr. Ball, correct?
A That's right.

Q So you're both doctors that your training as -- in anesthesiology is -- would you agree gives -- an anesthesiologist brings more pharmacological training and experience in the appropriate use of opioids?
A Yes.
Q Whereas an anesthesiologist does it primarily intraoperatively, correct?
A Mostly, yes.
Q Right. But they also have an important role in post-op pain, correct?
A That's right.
Q And a pain care specialist does it primarily in a private setting -- or an outpatient setting? I'm sorry.
A Most of the time, yes.
Q Now, from your review of the evidence, did the anesthesiologist know that Mr. Guthrie was on the 75 patch when he came in that day?
A Yes.
Q So he knew he was on the patch, correct?
A That's right.
Q And did Dr. Ballard know that he was on the patch that day, correct?
A Yes.
Q And did either of them discontinue the use-- Was it within the scope of the anesthesiologist at the time the

patient went home that he could have altered his home medications if he thought it was appropriate?

A It's possible, sure.

Q Right. Have you ever done that?

A Not that I recall.

Q And, anyhow, the home medications were not changed by either the anesthesiologist or the surgeon, correct?

A Correct.

Q And they both assessed him prior to surgery, correct?

A That's right.

Q And the patient was monitored, both pre-op, during surgery, Recovery I phase, Recovery II phase, correct?

A That's right.

Q And he was sent home in a stable condition, correct?

A That's right.

Q And from your review of the evidence, not that we're criticizing it, but did anybody contact Dr. Ball about whether -- what should or should not be his -- change of the post-op medications based upon what they found during surgery?

A No.

Q Have you ever been consulted while -- about post-op medications from an operating surgeon?

A Occasionally, sure.

MR. BROCK: Can we put up the exhibit from opening

for -- the demonstrative from opening with the 18 days? So -- And can you just go into the 18 days?

(Brief pause.)

BY MR. BROCK:

Q All right. So, just to be clear here, I know you've talked about -- you've talked about fatigue, and we've already talked about that fatigue, and I know you talked about rashes or itching, I think, that was seen or reported on the -- was it the 18th?

A Yes.

Q But in terms of -- other than that, in terms of -- again, to be clear of what Ms. Guthrie, who was with her husband almost 24/7, in terms of what she observed or what he relayed to her in terms of complications or complaints from -- all the way from March 14th to March -- the morning of March 23rd when he was assessed by the anesthesiologist, there were no complications or complaints, correct?

A Correct, other than what you've mentioned.

Q And that includes when she -- she was there when he spoke with the anesthesiologist and what the anesthesiologist -- part of the role of an anesthesiologist is to assess, "Is there something that makes this patient's respiratory status compromised?" Is that right?

A That's correct.

Q Including respiratory depression?

A That's right.
Q Or impending toxicity?
A It would be, hopefully, picked up by the anesthesiologist. I don't know that that's something they're always asking for, but that's certainly an evaluation that they maybe have picked up something at times.
Q As an anesthesiologist, you could sometimes have a person come in to you for surgery that might be too doped up, and you say, "We better wait and use something -- give them Narcan," correct?
A That's certainly possible.
Q What is Narcan?
A It's a specific antagonist drug to reverse the effects of opioids.
Q So did the -- from your review of the records, is there any indication -- well, there is no indication that the anesthesiologist saw anything about Mr. Guthrie's physical status that he needed to order Narcan to reverse any opiate or fentanyl patch toxicity, correct?
A That's correct.
Q Why did Mr. Guthrie stop taking Percocet?
A He said it upset his stomach.
Q Okay. Why did he stop making MS Contin?
A He was told to stop, from the emergency room when he went there after a seizure.

Q And as we discussed, why did he stop taking physical therapy?
A Financial reasons.
Q Okay. Why did he stop taking hydrocodone?
A He-- It didn't work very well.
Q Didn't touch his pain, correct?
A Correct.
MR. BROCK: Now, go to the demonstrative we provided to counsel that shows 2009 to 2014.
(Brief pause.)
MR. PATE: I don't recall seeing this.
MR. BROCK: Well, we went it to you along with our other demonstratives. There's nothing on it.
MR. PATE: That's right. That's fine. I don't remember seeing the report.
MR. BROCK: Can you show it to the jury? There's no objection.
THE COURT: Is there any objection?
MR. PATE: There's no objection, Your Honor.
THE COURT: All right. It may be shown to the jury. Are you going to seek to have it marked for ID purposes?
MR. BROCK: No, just-- Well, I guess we're-- Yes, I guess --
THE COURT: It looks like a calendar, if I'm guessing right.

MR. BROCK: Yes. I will mark it for identification purposes only. It's not going to be admitted. It's just a demonstrative.

THE COURT: Okay. So we'll mark it for ID purposes. What do you want to mark it? Do you know what your numbering system is?

MR. BROCK: I better report back to law school. I don't have a number. I'm sorry. Number 1?

THE COURT: Why don't we go with Defendant's ID 1.

(Defendant's Exhibit ID-1 was received for identification only.)

BY MR. BROCK:

Q So you did your report -- your initial certificate after reviewing the case. What was that time frame again?

A 2011.

Q All right. I believe it was February, February 7th, February 8th, 2011. Does that sound right? Oh, look at that. That's a 2/8. (Indicating.) Okay. I'm going to see if I can do it this way. 2/8. Okay?

A Okay.

Q All right, sir? When we took your deposition, you were not aware that Ms. Guthrie had filed a lawsuit against Watson Pharmaceutical, correct?

MR. PATE: Your Honor, I'm going to object. This is beyond the scope of direct.

MR. BROCK: This goes to the basis of his opinion, what he considered and did not consider.

MR. PATE: Rule 611.

THE COURT: I'm sorry? I couldn't hear you.

MR. PATE: Rule 611. Beyond the scope of direct. There were no questions that were asked about any -- anything pertaining to any lawsuit filed by Ms. Guthrie against anybody except for Dr. Ball.

THE COURT: I think there were questions asked about the scope of his work that would -- on cross that would allow this. And you can come back on redirect and follow up with anything. I think it's within the scope.

MR. PATE: Okay.

BY MR. BROCK:

Q And your deposition was taken on June 9th, was it?

A Yes.

Q Of '14. So that's-- Good gracious. I'm sorry. June the 9th and 2/8/11. And that is about three years and three months apart, correct?

A That's right.

Q And even though you've worked with Mr. Miller in over a hundred fentanyl patch cases -- and we've gone over at least 11 to 12 to 13 cases in which you've testified, including against the fentanyl manufacturer, correct?

A That's right.

Q You did not know or were not told by the attorneys for Ms. Guthrie that they had filed a lawsuit saying the cause of death was the patch?

A That's correct.

MR. BROCK: Your Honor, I'd like to ask the witness some questions about this complaint filed on March 11th, 2015, the month after that. This is dated 2/11.

MR. PATE: Again, Your Honor, I'll object as going beyond the scope of direct. He referred to the lawsuit. Now he wants to go into the details. There were actually no details discussed with Dr. Grubb on the record on any of the allegations contained in the lawsuit.

MR. BROCK: The cause of death was discussed.

THE COURT: I'll allow it.

MR. BROCK: Okay. I like to move that into evidence, Your Honor. I's already been subject to a motion in limine.

THE COURT: What number have you marked it as?

MR. BROCK: J-60.

MR. PATE: Subject to the Court's order on the motion in limine, we have no objection.

THE COURT: All right. It will be admitted.

(Joint Exhibit 60 was received into evidence.)

BY MR. BROCK:

Q All right.

Mr. Price, can you highlight -- first highlight the

style of the case, please?

You see the style, "Karen Guthrie, individually, on behalf of the Estate of Donald Guthrie, as Administrator, Plaintiff, versus Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Watson Laboratories, Inc.," one says Nevada, one says Delaware, "and Watson Pharma, Inc.," correct?

A Yes.

Q And it's filed--

Can you highlight that date, Mr. Price?

And that says March 15th of 2011. Do you see this?

Can you highlight the date, please?

A Yes, I see that.

Q All right. Where is Hamilton County, Tennessee?

A That's right here.

Q Thank you, sir. Now, going to the complaint, on Paragraph 17, I want to show you this allegation here --

And going on to the next page. And highlight it, please.

It says, "The defective condition of the patch was a cause of death and the damages claimed herein." Do you see that, sir?

A Yes.

Q And you were not aware the then -- that they filed a claim claiming a manufacturing defect, a failure to warn, and a design defect. Is that correct?

A That's correct.
Q I'd like to take your attention to -- beginning on Page 9 of 37.
Can we highlight that, please? No, no, 37(a), just Paragraph 37(a), right there. Highlight that, please.
And it says, "More specifically, the Watson negligence includes, without limitation, negligence in the following areas or in the following respects: Providing a misleading, inadequate, or insufficient warning regarding the patch." Do you see that, sir?
A Yes.
Q All right.
Let's go to the next page, please.
I want to just-- There's almost 20 allegations here, but in the interest of time, I just wanted to go to some of them.
Would you highlight Paragraph (b), please, B, as in boy?
What does that say, sir, that Ms. Guthrie -- in the lawsuit filed by her attorney says that Watson Pharmaceuticals failed to do?
A Do you want me to read the highlighted portion?
Q Yes, sir.
A "Failure to use due care in designing and manufacturing the patch."

MR. BROCK: Paragraph (c), will you highlight that, please, Mr. Price?
BY MR. BROCK:
Q What does that say?
A "Failure to use proper materials reasonably suited to the manufacture of the patch."
MR. BROCK: Paragraph (d), please. Highlight it.
BY MR. BROCK:
Q And read it, please?
A "Failure to provide to the FDA information or data relevant to the safety of the patch."
Q Paragraph (f)?
A "Not performing sufficient testing of the patch to confirm or ensure that it was safe for its intended use."
MR. BROCK: Paragraph (g), please. Highlight it.
BY MR. BROCK:
Q And can you read it for us, please?
A "Failure to use due care to test and inspect the patch to determine its durability and functionality for the purpose for which it was intended."
Q Paragraph (h)?
A "Failure to ensure the patch is made without seal or other defects."
Q Before we go on, Doctor, from the review of the materials employed to you, have you seen anything by any

health care provider that suggested that the patch must have leaked?

A Not that I recall.

Q Okay. Did you read Dr. Metcalfe's deposition?

A Yes.

Q It was played to the jury this morning and yesterday. As you sit here now, you don't recall anything being talked about that?

A From what I recall, maybe there was some comment made to Dr. Metcalfe or something written on some -- some document headed to the medical examiner's office, maybe a document that he reviewed, someone maybe handwrote something about a patch. That is something that sticks out in my head. But without having it right in front of me, I can't say for a fact that I remember that.

Q Well, do you recall seeing anything about whether Ms. Guthrie relayed to the medical examiner about information that one of the health care treaters you talked about today said that the patch must have leaked?

A Yeah, I vaguely remember something about that, and about her saying it was a heart attack. I mean, there were a number of things that were speculated right at the time of death that were in various documents that I've reviewed, but I can't remember exactly which documents those are right as I sit here.

Q Well, but, again, as an expert, what was your recollection of if or when Ms. Guthrie had a conversation with the medical examiner, or conversations?
A Without having that document right in front of me-- That is one page among thousands of pages I reviewed. I don't recall.
Q Well, would you agree that if there is a record that's part of the medical examiner's file that suggests that there's another cause of what caused the fentanyl patch which you think -- the fentanyl level being high, that's an important piece of information, is it not?
A Well, if there's evidence to that effect, but I certainly know that of all the -- all the documents I've reviewed, there was nothing that showed any evidence of a defective patch. So I would have remembered that.
Q I'm sorry. Is a lawsuit that says it caused the death not --
A I had no idea there was this lawsuit. This-- I can't be expected to know what someone does in a court, outside the documents that I've been asked to review for standards of care.
Q Let's try this. You say you had no idea there was a lawsuit, yet you've worked with him in over a hundred cases involving fentanyl patches, correct?
A That's right.

Q Did it ever -- did it ever occur to you to ask, respectfully, during that three-year period, "By the way, are you making a claim against the manufacturer?"
A It never occurred to me to ask because it had nothing to do with my review of standards of care. My job is to determine what the standard of care is. And the vast majority of the time, the standard of care was upheld. I didn't even ask in those cases if a claim was filed against Johnson & Johnson or again Mylan or against Watson. My job was to objectively determine what the standard of care was, whether it was upheld.
Q I thought you told us earlier today that in the majority of the cases you worked on, that your allegation was against the pharmaceutical company that --
A That's not true. That is not true. That's a mischaracterization of my testimony.
Q Well, which percentage of the hundred cases?
A I only reviewed a small handful of the cases as they related to the warnings themselves, and they're listed on there. I got deposed on every single one of them. The 90-plus other cases that I've reviewed have been purely standards of care, "Here's the medical records, Dr. Grubb. Tell us whether the standard of care was upheld or not."
Q But on the 13 cases we went over today, you'll stand by what you relayed to the jury about which involved the patch

or which involved the physician or a combination, correct?
A That's right.
Q And part of the -- and you're certainly not sitting there and saying that you're not aware that there was an issue that certain patches may have had problems with them? You're not saying you've ignorant of that information, are you?
A Well, I know many years ago there was an issue of defective patches. From what I recall, that was maybe in '05, '06. I don't recall that ever being said in '09.
Q Well, let's continue on. Let's go on to Paragraph (j). What does that say in the complaint they failed against the pharmaceutical company?
A "Misrepresenting that the patch is safe for use."
Q Paragraph (k)?
A "Inadequate or insufficient inspection for defects."
Q Paragraph (l)?
A "Inadequate and/or insufficient research into the safety of the product prior to sale."
Q And Paragraph (m)?
A "Inadequate and/or insufficient monitoring or research regarding adverse events."
Q And finally, Paragraph (o)?
A "Failure to provide adequate training, knowledge, or information to physicians, distributors, or sellers of the product."

Q In the interest of time, if I told you that this complaint also includes an allegation that the Watson Pharmaceutical Company misrepresented -- misled people, including Dr. Ball, on information, do you have any reason to dispute that that allegation is here, or would you like me to pull it up?
A No, we went over this in the deposition in great detail, and that was the first time I had seen that document.
Q June 9th, 2014?
A That's correct.
Q And you met with the attorneys the night before?
A I believe the morning of that deposition we -- we met for an hour or so.
Q To go over what some of your testimony may cover?
A Sure, documents I was bringing, et cetera.
Q I made reference here--
Can we go back to Exhibit J-50?
THE COURT: Mr. Brock, before we do that, because you look like you might be going back, it's a little after 5:00, how much longer do you have?
MR. BROCK: I have probably 10 to 15 minutes. I mean, I want to be respectful of the jury's time and also the witness's. And I don't know how much redirect there is.
THE COURT: Well, there will be redirect as well. From-- It sounds like that this witness could --

MR. PATE: For what it's worth, Your Honor, we're fine with going ahead and let Mr. Brock finish his examination and resume tomorrow morning.

THE COURT: Which would be fine, but I think we're not going to be able to finish within an hour. So we'll -- we'll take a break here and resume in the morning.

And I'm going to go ahead and release the jury. I know some of you have quite a way to drive.

(Brief pause.)

(The jury exited the courtroom, and the proceedings continued as follows:)

THE COURT: All right. Anything else that we need the address tonight? Obviously the rules apply with respect to sequestration of the witness. Is there anything else that needs to be addressed?

MR. MILLER: Can we let Dr. Grubb go before we speak, Your Honor?

THE COURT: Yes.

You're excused. You'll need to be back here at 9:00.

THE WITNESS: Okay. Thank you.

(Witness excused.)

THE COURT: All right.

MR. MILLER: Your Honor, I did want to raise one thing. Mr. Brock --

THE COURT: Is this about this witness? Then I won't hear from you. Mr. Pate is the only -- can raise something if there's a witness --

MR. PATE: I think what he's getting ready to work to is, Mr. Brock opened the door on the question of sleep apnea, which was in their motion in limine, and it reopens the door to Dr. Farr.

THE COURT: I don't know that it reopens the door to Dr. Farr. I'll hear from Mr. Brock on the issue.

MR. BROCK: It was first-- All right. They -- they questioned -- have done questioning about sleep apnea to this witness -- to my client as well as this witness. We have never asked the question about sleep apnea. It has come out that there is no diagnosis of sleep apnea. Once it's out there, I mean, I'm sorry --

(Off-the-record discussion.)

MR. BROCK: Our motion in limine, which was granted, was that they couldn't get up and make -- say that there was a diagnosis of sleep apnea because there never was a diagnosis of sleep apnea. Now, the fact that it's come out that he did not have a diagnosis of sleep apnea is not in contravention of the Court's ruling, but, rather, our concern and the motion in limine we filed was that they would improperly characterize that this is sleep apnea. Further, they've brought out emphasis relative to the sleep studies, like pointing out to

some of the recommendations of saying, "Oh, we've got to avoid opiates and alcohol," and want to give the impression that this gentleman had a condition more severe or some kind of untoward effect and yet ignore the reality is is, you know, that he did not have a diagnosis of sleep apnea and he really wasn't put on a C-PAP machine or things that are put up for a more serious condition. So, really the relief sought initially was us -- was not for them to say he had a diagnosis of it when there was no basis for it.

THE COURT: Well, I think if -- although no one's actually referring to the Court's ruling, it's Document 216. The ruling, in summary, was that Dr. Grubb couldn't testify regarding any opinion that Mr. Guthrie had sleep apnea and/or asthma because the plaintiff had not shown a sufficient factual basis for her experts to opine this.

I further said, "If the plaintiff believes that her experts do have sufficient factual basis to render a reliable opinion that Mr. Guthrie suffered from sleep apnea and/or asthma," the plaintiff was directed to raise the issue outside the presence of the jury. I don't know that there is reliable testimony at this point that Mr. Guthrie had those conditions. So far the testimony is that there was no diagnosis of that.

I think I also, in yet another motion in limine, ruled that observations related to difficulty sleeping or breathing problems would not be precluded by that ruling.

MR. PATE: I agree with that, Your Honor. I think the issue-- What I have tried to do is avoid even a reference to sleep apnea altogether, in light of the Court's ruling, in an abundance of caution. I think that Dr. Grubb, however -- he was asked a series of questions regarding his obesity, the COPD, and some of the other respiratory conditions we talked about. This is certainly-- He could be considered predisposed to sleep apnea. That's not the same as a diagnosis, but it's certainly something Dr. Grubb would be willing to testify to. And I wasn't going to elicit that testimony, in light of the Court's in limine ruling, but I think that by going and pointing out, "Well, in the sleep study there was no confirmed diagnosis of sleep apnea," that opens the door to our ability to --

THE COURT: Well, I don't think he can say he had sleep apnea to a reasonable degree of medical certainty, but you will be able on redirect to question him, follow up on anything that's brought up in his cross-examination. And I'll have to rule on it question by question.

MR. BROCK: Right. Your Honor, as I sit here -- because in realtime it's sometimes hard -- I did not ask whether he had sleep apnea. The witness volunteered it.

THE COURT: You have a transcript. Tomorrow you can point exactly where it came up. All right? So I'm not going to sit here and guess which one of your memories is better

suited.

Now, anything else?

MR. PATE: The only other thing, Your Honor, was that we think that with Mr. Brock going through line by line the allegations in this complaint with Dr. Grubb, he opened the door to the testimony that was -- that was given by Dr. Farr where he said six ways from Sunday there was absolutely no evidence of a defective patch in any way, shape, or form. And so that was the other -- that was the other issue that we wanted to raise.

THE COURT: Well, my understanding is, nobody is going to present any evidence that there was a defective patch. What I think he's opened the door up is to your client's explanation about the evidentiary admissions that have been made. Each side designated three experts. So we'll see where it goes. But at this point I'm not -- I'm not seeing that as a basis for you to bring in another expert. If it becomes a contention that the defendant contends there was a defective patch-- I can't even tell that they're asserting comparative fault anymore.

Is the defendant asserting any comparative fault?

MR. BROCK: We're not, Your Honor.

MR. PATE: Well, I think they're trying -- they're not asserting comparative fault, but they obviously want to leave the jury with the impression there was a defective patch

in this as a result of their allegations.

THE COURT: You'll be able to cover it on redirect, and you'll be able to cover it with your client, but at this point there is no basis for presenting that issue to the jury, you know, and what we're dealing with here, I think, is the Sixth Circuit's view of the evidentiary admission, and the fact that it gives you and your client the ability to explain. So you'll be able to cover it on -- on redirect. Now, from a-- Anything else?

(Brief pause.)

THE COURT: All right. Thus far, the parties have not actually moved to introduce evidence, and it's not in the record. And I'm not going to have the courtroom deputy and the court reporter continue to remind you of that. I reminded you before the lunch break. And after the lunch break, probably because we got started a little late, it wasn't addressed. But I'm going to direct you-all to come back here tomorrow morning at 8:30 and get together about what is admitted into evidence, what isn't admitted into evidence. And I think our court reporter has been kind enough to tell you more than once they don't transcribe the video that you play, so you're going to have a tremendous hole in your record if somebody doesn't take appropriate action to remedy the record.

So 8:30 for you, and we'll resume with the jury promptly at 9:00. And then it sounded like you have maybe two

and a half hours of deposition that you want to play. I'll remind the parties that they need to provide the transcript of any video deposition for ID purposes, which has not happened yet. The transcript that you gave me to rule on that one issue was not submitted for ID purposes. And then hopefully we'll get to another witness or two tomorrow as well, in order for us to conclude timely.

Now, I can ask the jury about staying later, but some of them have an hour drive. I've already told you that. I assume the lawyers wouldn't actually mind staying later, but I don't know whether the jury would. We don't usually ask them to stay tremendously late or get here early, under the circumstances of how long they're driving here. I don't really have a cure for that. So when we get close to 5:00, you-all should understand you need to wrap it up if that's what you're trying to do. All right.

(Evening recess.)